United States Department of Agriculture
Agricultural Marketing Service | National Organic Program
Document Cover Sheet
https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned

Document Type:

☒ **National List Petition or Petition Update**

A petition is a request to amend the USDA National Organic Program's National List of Allowed and Prohibited Substances (National List).

Any person may submit a petition to have a substance evaluated by the National Organic Standards Board (7 CFR 205.607(a)).

Guidelines for submitting a petition are available in the NOP Handbook as NOP 3011, National List Petition Guidelines.

Petitions are posted for the public on the NOP website for Petitioned Substances.

☐ **Technical Report**

A technical report is developed in response to a petition to amend the National List. Reports are also developed to assist in the review of substances that are already on the National List.

Technical reports are completed by third-party contractors and are available to the public on the NOP website for Petitioned Substances.

Contractor names and dates completed are available in the report.

NATIONAL ORGANIC PROGRAM (NOP)
NATIONAL ORGANIC STANDARDS BOARD (NOSB)

MATERIALS PETITION FOR THE NATIONAL LIST

REVISED ACTIVE INGREDIENT C_6, C_8, C_{10}, C_{12} - **NATURALLY DERIVED FATTY ALCOHOL**

GREEN AG SUPPLY, LLC

PETITIONER:

GREEN AG SUPPLY, LLC
PO BOX 386
CARY, NC 27512

SUBMITTER/CONSULTANT:

T. B. HARDING, JR., LVOG INC.
125 W. 7TH STREET
WIND GAP, PA 18091
12/7/18

LeHigh Valley Organic Growers, Inc.

125 West Seventh Street
Wind Gap, Pennsylvania 18091 USA

A Company of VOG, Inc.

Telephone: 610-863-6700
Facsimile: 610-863-4622
Email: tom@lehighvalleyorganicgrowers.com

December 7, 2018

Clarissa R. Mathews, Ph.D.
National List Manager
National Organic Program
1400 Independence Avenue, SW.
Room 2648-S STOP 0268
Washington, DC 20250-0268

Dear Dr. Mathews:

Per your letter of November 19, 2018 and our telephone conversation several days ago, please fine herewith our two (2) completely revised Flash Drives with the specific changes and additions reference points 1 – 3!

This Revised Petition is being submitted on behalf of the petitioner Green Ag Supply, LLC Active Material Naturally Derived Fatty Alcohol for Use on Organic Tobacco Crops.

Note the following critical points:

Point 1: Petitioned Active Ingredient C_6, C_8, C_{10}, C_{12} - **Naturally Derived Fatty Alcohol**, A Non-Formulated Ingredient, with the trade name Mascol 80.

Point 2: We have followed your suggestion by omitting Item B.6 and any further reference to the inert ingredient Tween 80.

Point 3: As in point (1) we have modified the petition to add the full range of fatty alcohol materials in Mascol 80 (i.e. Active Ingredient C_6, C_8, C_{10}, C_{12} **Naturally Derived Fatty Alcohol)** to ensure the appropriate materials are included in the review by the National Organic Standards Board (NOSB)

The following revisions have been made to the petition and are included in the flash drives being provided as the resubmission of this petition:

Page 1 – Item A.1 3rd line
Active Ingredient C_6, C_8, C_{10}, C_{12} **Naturally Derived Fatty Alcohol**

Item A.3 – no inert ingredients
(Omit information on Tween 80 pp 2-11)

Item B.1 page 2
Active Ingredient name C_6, C_8, C_{10}, C_{12} **Naturally Derived Fatty Alcohol**

Substance Common Name: hexanol, octanol, decanol, dodecanol

Note: the fatty alcohol active ingredient has a trade name of Mascol 80 and is **not a formulated ingredient/product!**

Page 6 – Item B.5

1. Active Ingredient C_6, C_8, C_{10}, C_{12} **Naturally Derived Fatty Alcohol** (Mascol 80) Safety Data Sheet
2. Active Ingredient C6, C_8, C_{10}, C_{12} **Naturally Derived Fatty Alcohol** Technical Specification Sheet. Naturally derived fatty alcohol ingredient has the trade name MASCOL 80.

Page 33 – Item B.6 Ancillary Substance: NONE

Page 58 – Item B.8 Active Substance
Active Ingredient C6, C_8, C_{10}, C_{12} Fatty Alcohol

Page 76-79 of previous petition omitted - Omit Polysorbate 80

Page 65 Item B.9
Active Ingredient C6, C_8, C_{10}, C_{12} **Naturally Derived Fatty Alcohol**

(Trade name is MASCOL 80)
Omit – EPA Chemical Numbers

Page 124 – Item B.11
Active Ingredient C6, C_8, C_{10}, C_{12} **Naturally Derived Fatty Alcohol**
Trade Name for this ingredient is MASCOL 80.

Page 265 – Item B.13
National List Section 205.601 (k) (2) Active Ingredient C_6, C_8, C_{10}, C_{12} **Naturally Derived Fatty Alcohol.**

PLEASE NOTE:

It is important to point out that in the report "2018 NC State University Field Testing at the Rocky Mount Research Station and the Oxford Tobacco Research station, NC" (see pages 277-284 in this petition) was updated to include yield, quality and value of tobacco when comparing fatty alcohols to alternative oil products. Results showed that cured leaf yield and value were maximized in treatments comprised of natural derived fatty alcohol. All other treatments resulted in similar yield and value to the non-treated control (ie. Statistically significant loss in yield and value).

We are pleased to learn that this Revised Petition will go forward for a final review and vote by the National Organic Standards Board (NOSB).

Please advise us ASAP when this material will be placed before NOSB for a final vote so we can bring our team together to attend and make Public Comments at the NOSB meeting.

Thank you very much for your specific guidance and information.

Sincerely,

LVOG, Inc.

Thomas B Harding

Thomas B. Harding, Jr.
President
Organic Program Consultant
Green Ag Supply LLC

National List Category Being Petitioned

ITEM A.1 - Substance Petition Section

Category: Synthetic Substance Allowed for Use in Organic Crop Production

NOP Reference: 205.601(k) – As Plant Growth Regulator

NOP Section: 205.601 (k) (2) – Active Ingredients C_6, C_8, C_{10}, C_{12} - **Naturally Derived Fatty Alcohol**

ITEM A.2 - OFPA Category: Crop and Livestock Materials

Category: Production Aids (Organic Tobacco)

Annotation: for Use in Organic Tobacco Production

ITEM A.3 - Inert Ingredients:

NONE

ITEM B.1 Substance Name

Active Ingredient Name: C_6, C_8, C_{10}, C_{12} **- Naturally Derived Fatty Alcohol**

Substances Common Name: hexanol, octanol, decanol, dodecanol

Note: the fatty alcohol active ingredient has a trade name of (MASCOL 80) and is not a formulated ingredient/product.

CAS # 68603-15-6

EINES # 271-642-9

ITEM B.2 Petitioner and Manufacturer Information

Petitioner:
Green Ag Supply, LLC
PO Box 386
Cary, NC 27512
919-467-1599

Manufacturer:
ICOF America, Inc.
5420 North Bend Road
Suite 202
Cincinnati, OH 45247
513-741-6813

ITEM B.3 Intended or Current Use:

Sucker control on tobacco

The tobacco plant grows with a single stem having a terminal (apical) bud which is apically dominant. Eventually, the terminal vegetative bud develops into a reproductive bud that produces flowers. If the seed head is allowed to develop, lateral buds (suckers) begin to grow in the leaf axils. If the terminal bud is removed (topped), which is the normal practice, the suckers in comparison grow very rapidly and if not controlled or removed, rob the marketable leaves from obtaining a good yield.

Most growers and tobacco buyers have found that removal of the tops along with the removal or restriction of growth of suckers result in desirable changes in the cured leaf. Experiments have shown that manual topping and hand suckering lead to an increase in root growth. This, in turn, increases the plant’s potential to adsorb water and nutrients and to synthesize nicotine. Also, topping and suckering reduce the weight at the top of the plant which makes the plant less likely to blow over during windstorms. The practice of topping and suckering reduces the drain on the leaves of certain organic and in organic compounds used for growth by the plant; therefore, this practice can be expected to increase the weight and body of the leaves and to change their chemistry, especially those produced in the upper leaf positions.

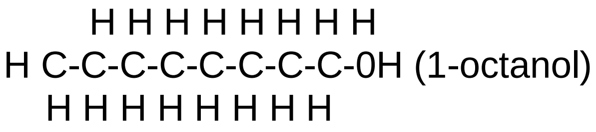
ITEM B.4 Intended Activities and Application Rate:

Sucker control on organic tobacco crops: 4-6% solution of the formulated product applied directed broadcast over the top of tobacco plants in the early button to early flower stage of growth when suckers, axillary buds are succulent tender, utilizing 50 gallons of spray solution per acre.

Mode of Action:

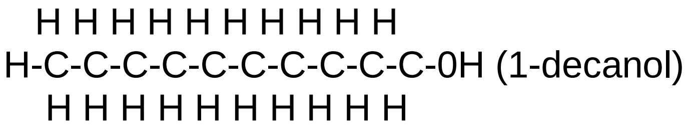
Upon contacting the axillary buds/suckers at the leaf axils, the solution containing the active substance quickly dissolves the thin undeveloped cuticle or waxy area and results in desiccation of the axillary bud/ sucker by rupturing cell walls and rapidly evaporating liquids.

Chemical Structure:



$$\begin{array}{l} \quad\ \text{H H H H H H H H} \\ \text{H C-C-C-C-C-C-C-C-0H} \\ \quad \text{H H H H H H H H} \end{array}$$

(1-octanol)



$$\begin{array}{l} \ \text{H H H H H H H H H H} \\ \text{H-C-C-C-C-C-C-C-C-C-C-0H} \\ \quad \text{H H H H H H H H H H} \end{array}$$

(1-decanol)

ITEM B.5 Manufacturing Process:

The alcohols derived from natural sources are generally isolated from any of a variety of natural occurring fats, oils and waxes of either animal or vegetable origin. The most commonly used sources are coconut oil, palm kernel oil, palm oil, lard and tallow. The alcohols are prepared by a transesterification of the fatty acids in the triglycerides found in natural oils and fats followed by a catalytic hydrogenolysis of the resulting esters. Purification and fraction of the resulting alcohols is similar to the synthetically produced materials.

Included below is the diagram of the fatty alcohol process flow, as well as the process flow for palm oil.

Also, included are the following information for the substance fatty alcohols:

1. Active Ingredients C_6, C_8, C_{10}, C_{12} - **Naturally Derived Fatty Alcohol** (Mascol 80) Safety Data Sheet
2. Active Ingredients C_6, C_8, C_{10}, C_{12} - **Naturally Derived Fatty Alcohol** Technical Specification Sheet. **Naturally Derived Fatty Alcohol** has the trade name (MASCOL 80).
3. Raw Material Palm Kernel Oil sustainability certification documents

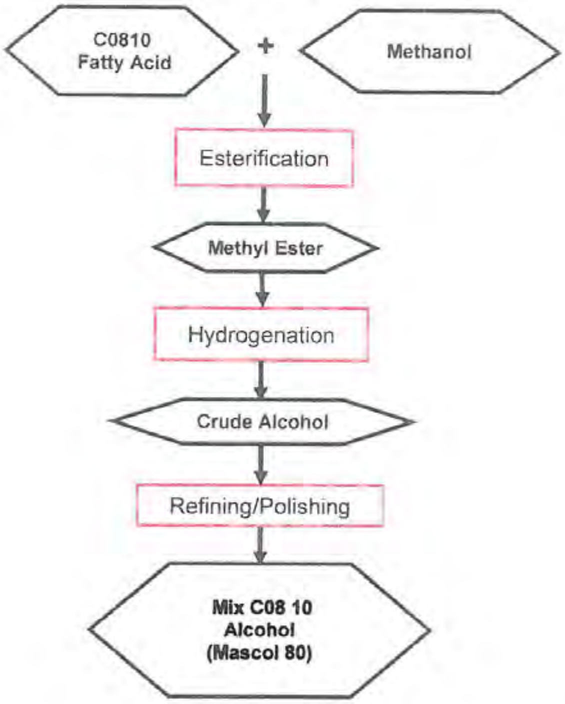
PT. MUSIM MAS

Head Office: Jl. K.L. Yos Sudarso Km. 7,8
Tanjung Mulia - Medan 20241
Sumatera Utara - Indonesia
Tel: (62-61) 6615511 - 6619866
Fax: (62-61) 6613060 - 6617386

Factory: Jl. Oleo, Kawasan Industri Medan II
Saentis - Percut Sei Tuan, Deli Serdang
Medan 20371 - Indonesia
Tel: (62-61) 6871123
Fax: (62-61) 6871152 - 6871153
Email: oleo@musimmas.com

Fatty Alcohol Process Flow

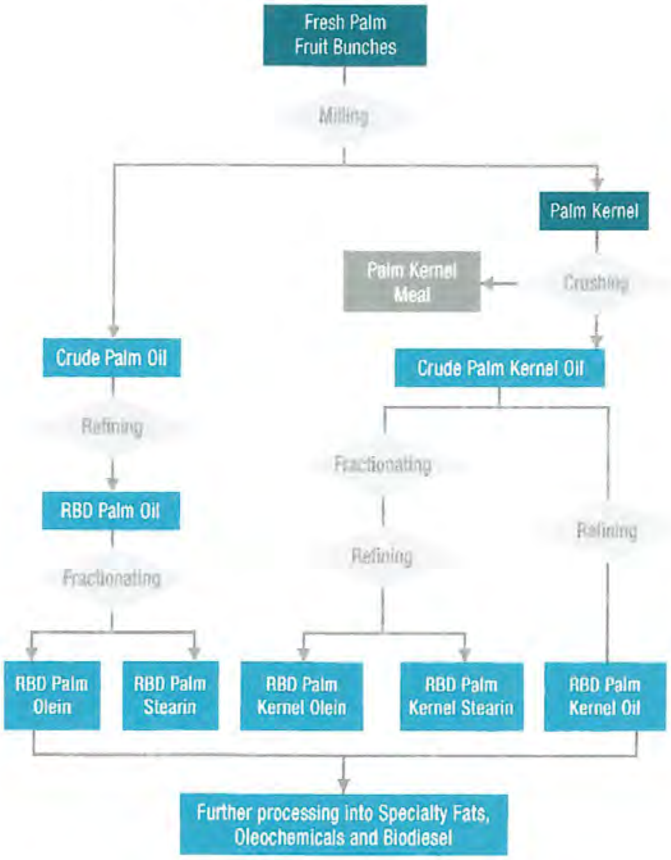
Process Flow



Prepared by:

Eng Bung Kiang
QA Manager
1-Jan-2017

Below is general information regarding the production of palm oil. Our palm oil, laurics and related products are widely used in many industries including food manufacturing, cosmetics and pharmaceutical industries.



a) Processing FFBs into crude palm oil and palm kernel

The process begins with the harvesting of fresh fruit bunches (FFBs) which are milled within 24 hours from harvesting. FFBs are first transferred to the palm oil mills for sterilisation by applying high-pressure steam, whereupon the palm fruits are enzyme deactivated and separated from the palm bunches.

After the steaming process, the palm fruitlets are crushed in a pressing machine to obtain crude palm oil and palm kernel. Waste and water is then cleared and separated from the CPO by means of a centrifuge. The cleared crude palm oil emerging from the centrifuge is then sent for refining while the palm kernel nut is sent for crushing. The empty fruit bunches and liquid waste arising from the process are used as fertiliser in the plantations.

b) Crushing palm kernel into crude palm kernel oil

The palm kernel nut is fractured causing the palm kernel within the shell to contract away from the shell. The shell is separated from the kernel through a clay bath where it is used as fuel in the boiler room or co-generation plant.

The palm kernel is further crushed to produce crude palm kernel oil and the remaining palm kernel meal is used as animal feed.

c) Refining process to obtain RBD palm oil and RBD palm kernel oil

To produce refined oil, crude palm oil and crude palm kernel oil is processed through three refining stages, namely degumming, bleaching and deodorising. In degumming, the gum and fatty acid in crude palm oil and crude palm kernel oil are separated together with other impurities such as trace minerals, copper and iron by the application of phosphoric acid.

In bleaching, the oil is mixed with bleaching earth (bentonite calcium) in a vacuum room to remove impurities and colour pigments in the palm oil. In deodorising, the odour and taste of the oil is removed when the oil is steamed at high temperatures between 240°C to 260°C and then cooled to room temperature.

b) Fractionating process into RBD stearin and RBD olein

RBD palm stearin and RBD palm olein are obtained by the fractionation of RBD palm oil; whereas RBD palm kernel stearin and RBD palm kernel olein are obtained by the fractionation of RBD palm kernel oil. Through a process known as crystallisation, RBD oil is cooled until crystals are formed.

The crystallized oil in the crystallizer is then filtered through a membrane to separate the liquid fraction i.e. olein from the solid fraction i.e. stearin. RBD palm olein is usually sold as cooking oil and may go through further fractionation.

Thanks,

John Schnieder

ICOF America Inc
10979 Reed Hartman, Suite 109
Cincinnati, OH 45242

Email: john.schnieder@icofgroup.com
Office: 513-791-1782
Main: 513-791-6813
Mobile: 513-746-7663
Fax: 513-791-2767
Internet: www.icofgroup.com

A member of the Musim Mas Group

PT. MUSIM MAS
Fatty Alcohol, Methyl Esters and Derivatives

SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Product Identification

Product Name	: Octyl Decyl Alcohol
Trade Name	: MASCOL 80
Other Identifier	: Alcohols C6-C12, 1-Octanol+1-Decanol.
Recommended Use	: Cosmetic base product for industrial purpose. General chemicals, as they are used in many ways in the chemicals industry.

Company Identification

Manufacturer Name	: PT Musim Mas
Address	: Jl. Oleo, Kawasan Industri Medan II, Saentis - Percut Sei Tuan, Deli Serdang Medan 20371 - Indonesia
Telephone Number	: 62-61-6871123
Fax Number	: 62-61-6871152 / 6871153
Email Address	: *oleo@musimmas.com*
Emergency Telephone Number	: +62-8116054139

2. HAZARD IDENTIFICATION

GHS Classification	
Physical Hazard	: Not classified as hazardous substance
Health Hazard	: Serious eye damage / eye irritation, Category 2
Environmental Hazard	: Not classified as hazardous substance
GHS Label Element	
Hazard Symbol	:

Signal Word	: Warning
Hazard Statement	: H319 Causes Serious eye irritation
Precautionary Statement	: P264 Wash hands thoroughly after handling. P280 Wear protective gloves/protective clothing/eye protection P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention.
Other Hazard	: No information available

PT. MUSIM MAS
Fatty Alcohol, Methyl Esters and Derivatives

SAFETY DATA SHEET

3. COMPOSITION/ INFORMATION ON INGREDIENTS

Substance

Chemical Name : Alcohols,C6-C12
Synonym : Octyl Decyl alcohol.
CAS No : 68603-15-6
EINECS No : 271-642-9
Ingredients or impurities that contribute to hazard : This product doesn't have impurities that contribute to the hazard classification.

4. FIRST AID MEASURES

Eye Contact : Rinse cautiously with water for several minutes, Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists, get medical advice/attention.
Skin Contact : Gently wash with plenty of soap and water.
Ingestion : Call a POISON CENTER or doctor/physician if you feel unwell.
Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing.

Most important symptomps/effects,accute and delayed
: No information available

Indication of immediate medical attention and special treatment needed
: No information available

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media : Powder, alcohol resistant foam, carbon dioxide.
Unsuitable Extinguishing Media : No information available
Specific hazards arising from the substances or mixture : Combustible material, vapours are heavier than air and may spread along floors. Forms explosive mixtures with air on intense heating. Development of hazardous combustion gases or vapours possible in the event of fire.
Special Protective equipment for fire-fighters : Use safety goggles in combination with dust mask, and other protection as appropriate to situation
Special Protective action for fire-fighters ; : Keep away from source of ignition and use appropriate extinguishing media. Fight fire from upwind position if possible.

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Fatty Alcohol, Methyl Esters and Derivatives

SAFETY DATA SHEET

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Use safety goggles and protective gloves. Large spills : Remove person to safety. Ensure adequate ventilation.
Environmental precautions	: Avoid release to the environment.
Methods and materials for containment and cleaning up	: Small spills : Absorb spills with sand, inert absorbent, waste cloth or sawdust. Then wipe up remainder in waste cloth. Large spills : Dike spills and dispose of in safe area.

7. HANDLING AND STORAGE

Precautions for safe Handling	: Use an adequate ventilation. Wash thoroughly after handling. Used personal protective equipment as required.
Conditions for safe storage including any incompatibilities	: Store container tightly closed in well-ventilate place. Do not store together with oxidizing agents. Keep away from source of ignitions.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Appropriate Engineering Controls	: Facilities storing or utilizing this materials should be equipped with an eyewash facilities and safety shower

Individual Protection Measures, such as personal protective equipment

Eye/Face Protection	: Tightly seal safety glasses.
Skin Protection	: Wear suitable protective clothing and glove (butyl rubber, nitrile rubber).
Respiratory Protection	: If technical suction or ventilation measures are not possible or are insufficient, protective breathing apparatus must be worn.
Thermal Hazards	: Not applicable
Environmental Exposure Controls	: Do not empty into drains.

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Fatty Alcohol, Methyl Esters and Derivatives

SAFETY DATA SHEET

9. PHYSICAL AND CHEMICAL PROPERTIES

Basic Information

Appearance	
Physical State	: Liquid
Colour	: Colourless
Odour	: Fishy alcohol
Odour threshold	: No information available
pH	: No information available
Melting Point/freezing point	: -11°C
Initial Boiling point and boiling range	: 204 - 238°C @ 1 atm
Flash point	: 96°C PMCC
Evaporation Rate	: No information available
Flammability (solid,gas)	: No information available
Upper/lower flammability or explosive limits	: No information available
Vapour pressure	: 0.058mmHg (7.7 Pa) at 24°C
Vapour density	: No information available
Relative density	: 0.818 g/cm³ @ 30°C
Solubility	: Water solubility : < 500 mg/L at 25°C Solvent solubility : Soluble in general organic solvent
Partition coefficient :n-octanol/water	: log Pow : 3.5 - 4.7
Auto-ignition temperature	: Approx 260°C
Decomposition temperature	: No information available
Viscosity	: 8 mPa.s (30°C)
Explosive properties	: No information available
Oxidizing properties	: No information available
Other Information	: No information available

10. STABILITY AND REACTIVITY

Reactivity	: Stable in general
Chemical stability	: Stable in general
Possibility of hazardous reactions	: No information available
Conditions to avoid	: Do not expose to extreme heat or flame
Incompatible materials	: Strong oxidizing agents
Hazardous decomposition products	: Carbon Monoxide Complete combustion forms carbon dioxide and water. Partial combustion also forms carbon monoxide, soot, aldehydes and ketones

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11. TOXICOLOGICAL INFORMATION

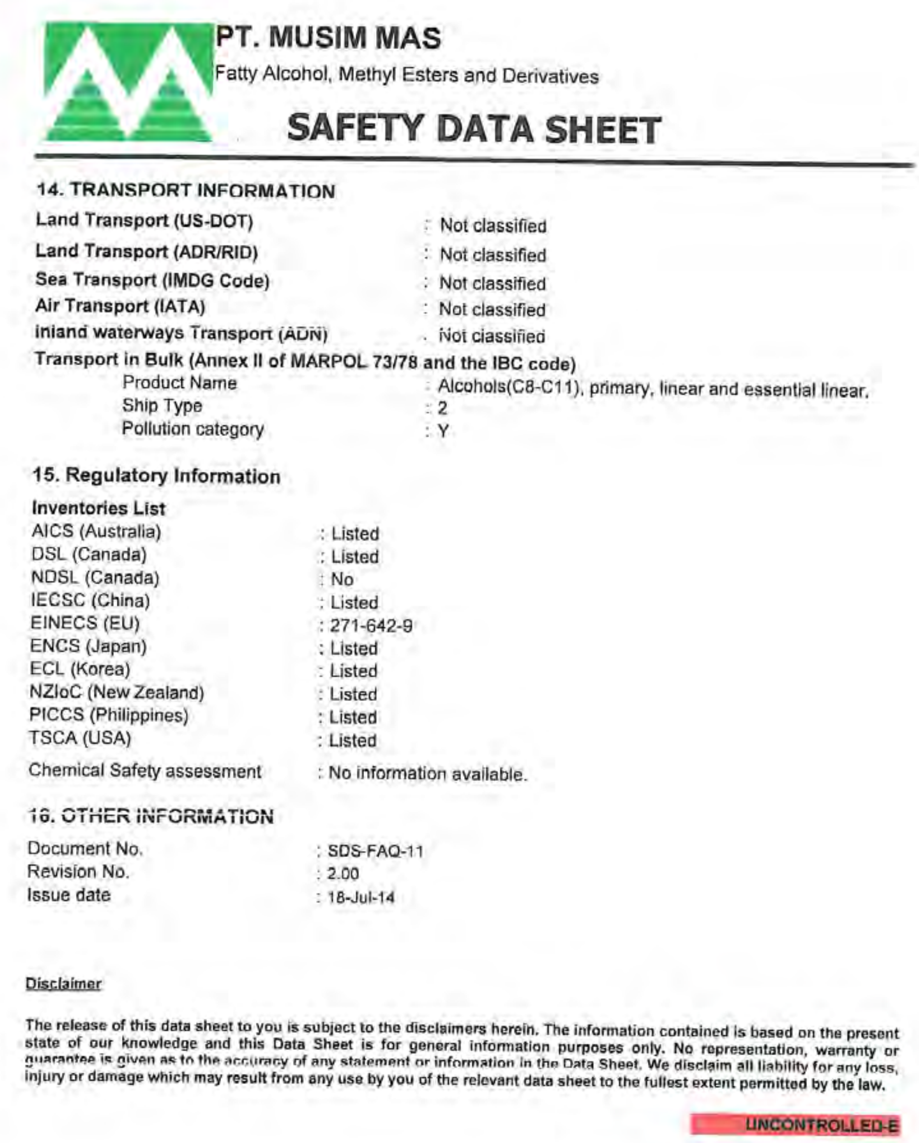
Acute toxicity : Oral : Rat, LD50 > 5000 mg/kg
Dermal: Rabbit, LD50 2000 mg/kg
Inhalation: No information Available
Skin corrosion/irritation : Rabbit, slight irritating
Serious eye damage/irritation : Rabbit, irritating
Respiratory or skin sensitization : Negative
Mutagenicity : Negative
Carcinogenicity : Negative
Reproductive toxicity : Negative
STOT-single exposure : No information available
STOT-repeated exposure : No information available
Aspiration Hazard : No information available

12. ECOLOGICAL INFORMATION

Ecotoxicity : LC50
Species : Pimephales promelas
Dose : 2.3 mg/L
Exposure time : 96 h
EC50
Species : N. Spinipes
Dose : 3.1mg/L
Exposure time : 96 h
Persistence and Degradability : Readily biodegradable
Bioaccumulative potential : Octanol-water partition coefficient : log Pow: 3.15-4.57
Mobility in soil : No information available
Result of the PBT and vPvB assessment : No information available
Other adverse effects : Additional ecological information : Do not allow to run into surface waters, wastewater or soil.

13. DISPOSAL CONSIDERATIONS

Disposal methods : Dispose of content/container to an approved waste disposal plant. Dispose only in accordance with local, state and federal regulations. Do not dispose via sinks, drains or into the immediate environment.



PT. MUSIM MAS
Fatty Alcohol, Methyl Esters and Derivatives

SAFETY DATA SHEET

14. TRANSPORT INFORMATION

Land Transport (US-DOT)	: Not classified
Land Transport (ADR/RID)	: Not classified
Sea Transport (IMDG Code)	: Not classified
Air Transport (IATA)	: Not classified
Inland waterways Transport (ADN)	: Not classified

Transport in Bulk (Annex II of MARPOL 73/78 and the IBC code)

Product Name	: Alcohols(C8-C11), primary, linear and essential linear.
Ship Type	: 2
Pollution category	: Y

15. Regulatory Information

Inventories List

AICS (Australia)	: Listed
DSL (Canada)	: Listed
NDSL (Canada)	: No
IECSC (China)	: Listed
EINECS (EU)	: 271-642-9
ENCS (Japan)	: Listed
ECL (Korea)	: Listed
NZIoC (New Zealand)	: Listed
PICCS (Philippines)	: Listed
TSCA (USA)	: Listed
Chemical Safety assessment	: No information available.

16. OTHER INFORMATION

Document No.	: SDS-FAQ-11
Revision No.	: 2.00
Issue date	: 18-Jul-14

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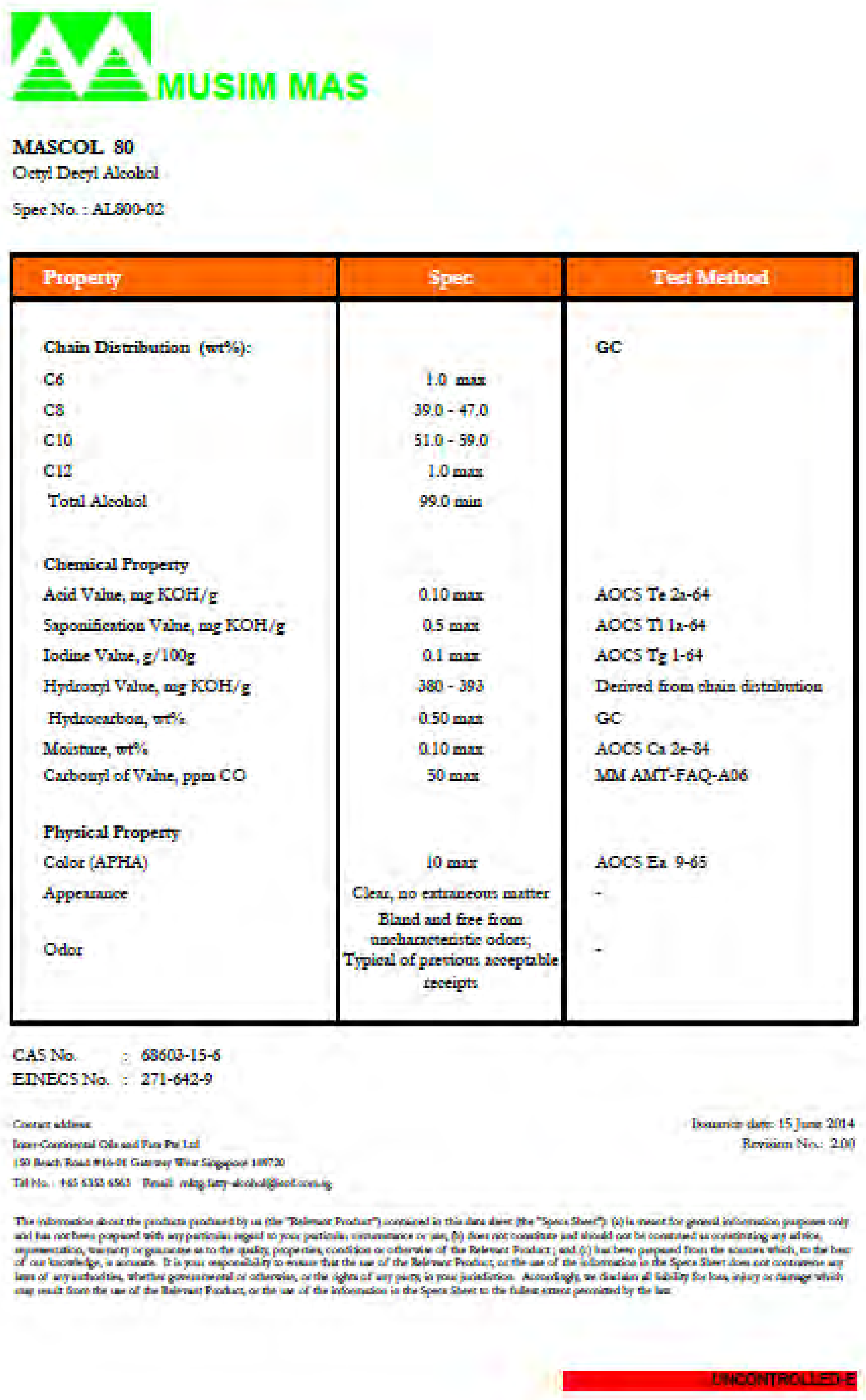

MUSIM MAS

MASCOL 80
Octyl Decyl Alcohol

Spec No. : AL800-02

Property	Spec	Test Method
Chain Distribution (wt%):		GC
C6	1.0 max	
C8	39.0 - 47.0	
C10	51.0 - 59.0	
C12	1.0 max	
Total Alcohol	99.0 min	
Chemical Property		
Acid Value, mg KOH/g	0.10 max	AOCS Te 2a-64
Saponification Value, mg KOH/g	0.5 max	AOCS Tl 1a-64
Iodine Value, g/100g	0.1 max	AOCS Tg 1-64
Hydroxyl Value, mg KOH/g	380 - 393	Derived from chain distribution
Hydrocarbon, wt%	0.50 max	GC
Moisture, wt%	0.10 max	AOCS Ca 2e-84
Carbonyl of Value, ppm CO	50 max	MM AMT-FAQ-A06
Physical Property		
Color (APHA)	10 max	AOCS Ea 9-65
Appearance	Clear, no extraneous matter	-
Odor	Bland and free from uncharacteristic odors; Typical of previous acceptable receipts	-

CAS No. : 68603-15-6
EINECS No. : 271-642-9

Contact address:
Inter-Continental Oils and Fats Pte Ltd
150 Beach Road #16-01 Gateway West Singapore 189720
Tel No. : +65 6355 6563 Email : mktg.fatty-alcohol@icof.com.sg

Issuance date: 15 June 2014
Revision No.: 2.00

The information about the products produced by us (the "Relevant Product") contained in this data sheet (the "Specs Sheet"): (a) is meant for general information purposes only and has not been prepared with any particular regard to your particular circumstance or use; (b) does not constitute and should not be construed as constituting any advice, representation, warranty or guarantee as to the quality, properties, condition or otherwise of the Relevant Product ; and (c) has been prepared from the sources which, to the best of our knowledge, is accurate. It is your responsibility to ensure that the use of the Relevant Product, or the use of the information in the Specs Sheet does not contravene any laws of any authorities, whether governmental or otherwise, or the rights of any party, in your jurisdiction. Accordingly, we disclaim all liability for loss, injury or damage which may result from the use of the Relevant Product, or the use of the information in the Specs Sheet to the fullest extent permitted by the law.

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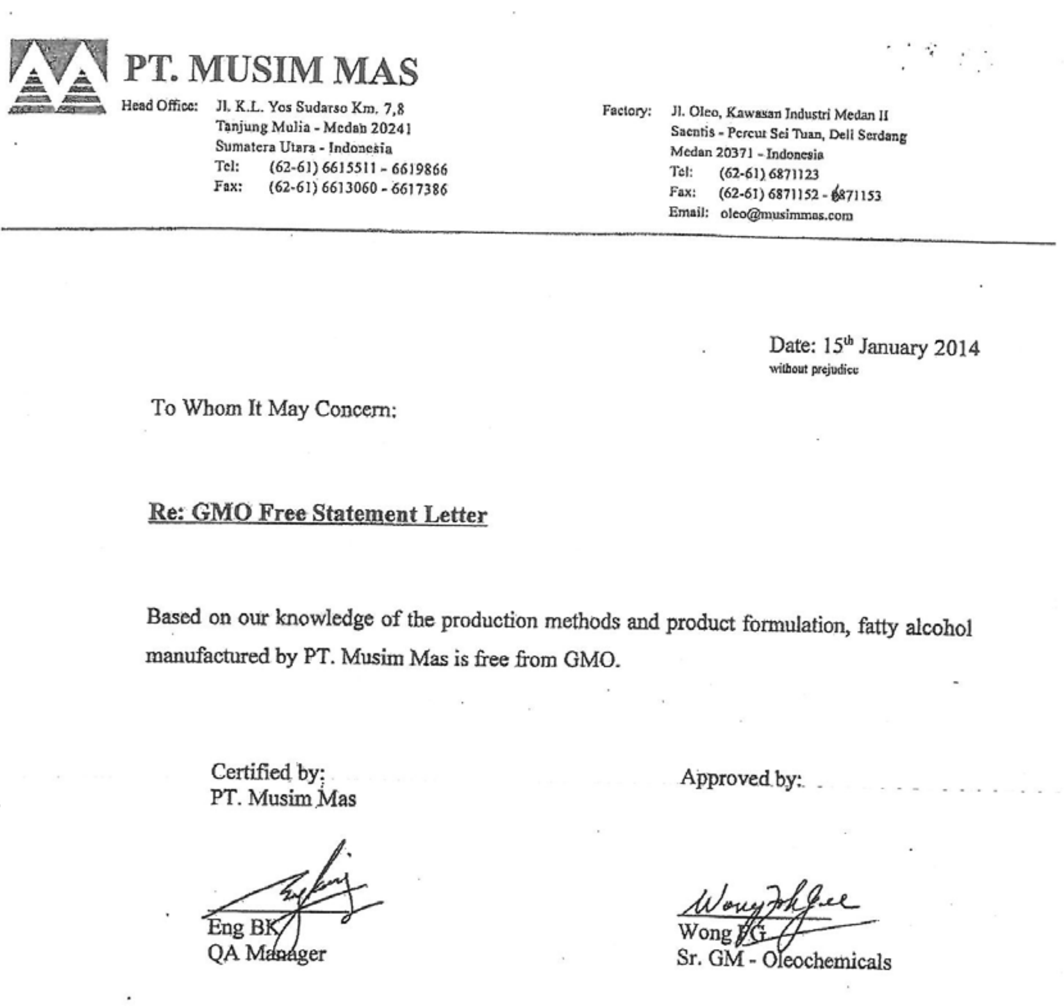
Manufacturing Process ‘Continued”

- **GMO Free Statement Letter for Mascol 80**
- **Compliance with RSPO (Roundtable on Sustainable Palm Oil) Supply Chain Certification Systems**
- **Kosher Certificate**
- **SGS Certification – GMP Codex Alimentarius**
- **Certificate of Accreditation KAN**
- **SGS Certification – ISO 14001: 2004**
- **SGS Certification – OHSAS 18001: 2007**
- **SGS Certification – ISO 9001 : 2008**
- **Mascol 80 Declaration Letter**
- **Mascol 80 Safer Chemical Declaration Letter**
- **Derivative Declaration Letter**



PT. MUSIM MAS

Head Office: Jl. K.L. Yos Sudarso Km. 7,8
Tanjung Mulia - Medan 20241
Sumatera Utara - Indonesia
Tel: (62-61) 6615511 - 6619866
Fax: (62-61) 6613060 - 6617386

Factory: Jl. Oleo, Kawasan Industri Medan II
Saentis - Percut Sei Tuan, Deli Serdang
Medan 20371 - Indonesia
Tel: (62-61) 6871123
Fax: (62-61) 6871152 - 6871153
Email: oleo@musimmas.com

Date: 15th January 2014
without prejudice

To Whom It May Concern:

Re: GMO Free Statement Letter

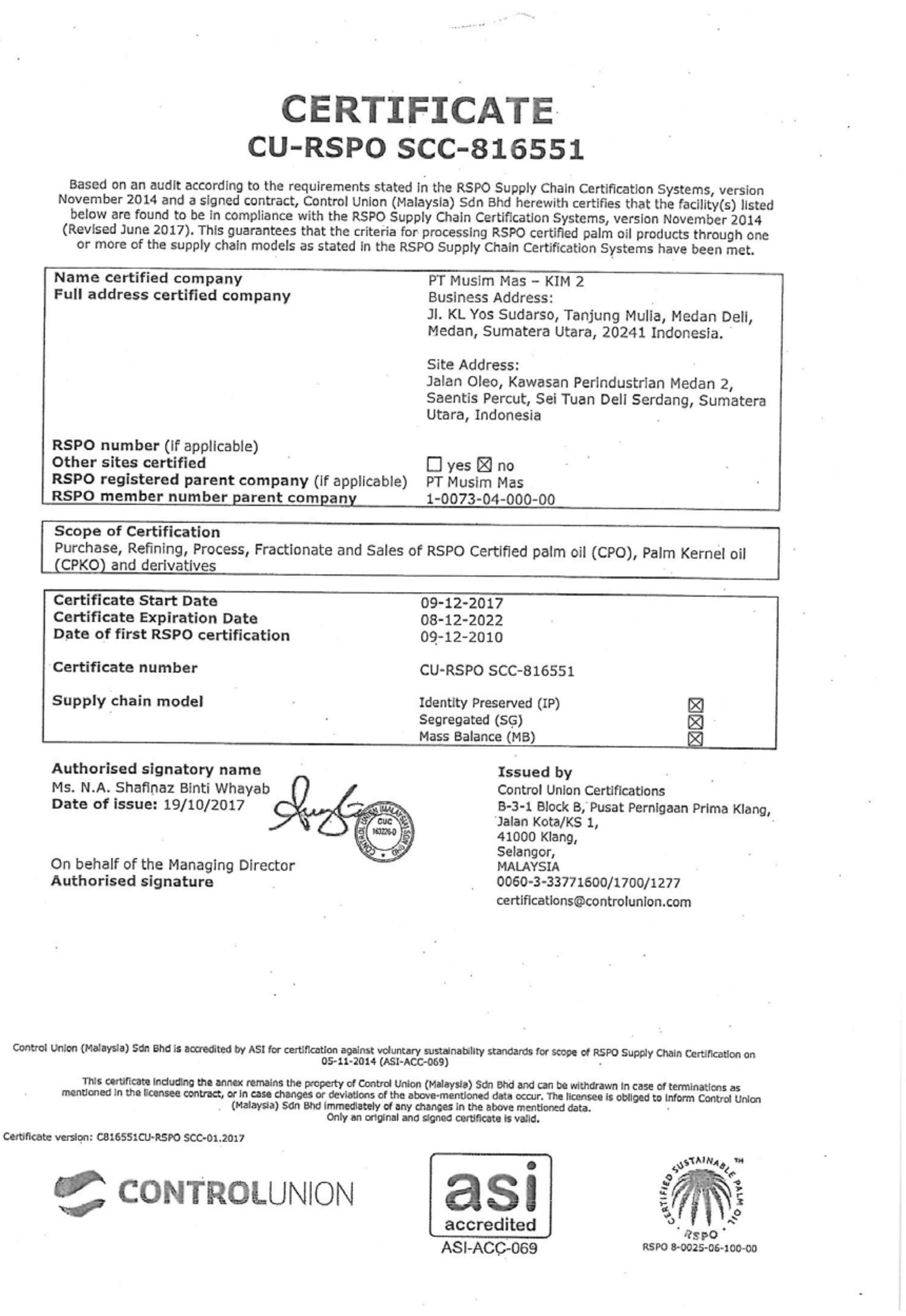
Based on our knowledge of the production methods and product formulation, fatty alcohol manufactured by PT. Musim Mas is free from GMO.

Certified by:
PT. Musim Mas

Eng BK
QA Manager

Approved by:

Wong FG
Sr. GM - Oleochemicals



CERTIFICATE

CU-RSPO SCC-816551

Based on an audit according to the requirements stated in the RSPO Supply Chain Certification Systems, version November 2014 and a signed contract, Control Union (Malaysia) Sdn Bhd herewith certifies that the facility(s) listed below are found to be in compliance with the RSPO Supply Chain Certification Systems, version November 2014 (Revised June 2017). This guarantees that the criteria for processing RSPO certified palm oil products through one or more of the supply chain models as stated in the RSPO Supply Chain Certification Systems have been met.

Name certified company	PT Musim Mas – KIM 2
Full address certified company	Business Address: Jl. KL Yos Sudarso, Tanjung Mulia, Medan Deli, Medan, Sumatera Utara, 20241 Indonesia. Site Address: Jalan Oleo, Kawasan Perindustrian Medan 2, Saentis Percut, Sei Tuan Deli Serdang, Sumatera Utara, Indonesia
RSPO number (if applicable)	
Other sites certified	☐ yes ☒ no
RSPO registered parent company (if applicable)	PT Musim Mas
RSPO member number parent company	1-0073-04-000-00

Scope of Certification

Purchase, Refining, Process, Fractionate and Sales of RSPO Certified palm oil (CPO), Palm Kernel oil (CPKO) and derivatives

Certificate Start Date	09-12-2017	
Certificate Expiration Date	08-12-2022	
Date of first RSPO certification	09-12-2010	
Certificate number	CU-RSPO SCC-816551	
Supply chain model	Identity Preserved (IP)	☒
	Segregated (SG)	☒
	Mass Balance (MB)	☒

Authorised signatory name
Ms. N.A. Shafinaz Binti Whayab
Date of issue: 19/10/2017

On behalf of the Managing Director
Authorised signature

Issued by
Control Union Certifications
B-3-1 Block B, Pusat Pernigaan Prima Klang,
Jalan Kota/KS 1,
41000 Klang,
Selangor,
MALAYSIA
0060-3-33771600/1700/1277
certifications@controlunion.com

Control Union (Malaysia) Sdn Bhd is accredited by ASI for certification against voluntary sustainability standards for scope of RSPO Supply Chain Certification on 05-11-2014 (ASI-ACC-069)

This certificate including the annex remains the property of Control Union (Malaysia) Sdn Bhd and can be withdrawn in case of terminations as mentioned in the licensee contract, or in case changes or deviations of the above-mentioned data occur. The licensee is obliged to inform Control Union (Malaysia) Sdn Bhd immediately of any changes in the above mentioned data.
Only an original and signed certificate is valid.

Certificate version: C816551CU-RSPO SCC-01.2017

CONTROLUNION

asi accredited
ASI-ACC-069

CERTIFIED SUSTAINABLE PALM OIL
RSPO
RSPO 8-0025-06-100-00

Annex 1 to Certificate – RSPO SCC

Certificate No.: CU-RSPO SCC-816551

CU Code:	*Name of facility:*	*Location address:*
REF 01	PT. Musim Mas KIM 2- Oleochemical	Jalan Oleo, Kawasan Perindustrian Medan 2, Saentis Percut, Sei Tuan Deli Serdang, Sumatera Utara, Indonesia.
REF 02	PT. Musim Mas KIM 2- Refinery division	Jalan Oleo, Kawasan Perindustrian Medan 2, Saentis Percut, Sei Tuan Deli Serdang, Sumatera Utara, Indonesia.

Authorised signatory name
Ms. N.A. Shafinaz Binti Whayab
Date of issue: 19/10/2017

On behalf of the Managing Director
Authorised signature

Issued by
Control Union Certifications
B-3-1 Block B, Pusat Pernigaan Prima Klang,
Jalan Kota/KS 1,
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This certificate including the annex remains the property of Control Union (Malaysia) Sdn Bhd and can be withdrawn in case of terminations as mentioned in the licensee contract, or in case changes or deviations of the above-mentioned data occur. The licensee is obliged to inform Control Union (Malaysia) Sdn Bhd immediately of any changes in the above mentioned data.
Only an original and signed certificate is valid.

Certificate version: C816551CU-RSPO SCC-01.2017

ASI-ACC-069

RSPO 8-0025-06-100-00

בס"ד

KOSHER CERTIFICATION
Rabbi Don Yoel Levy
Kashruth Administrator

KOSHER CERTIFICATE

KC# 5334770 - 1
18 Adar, 5778
March 5, 2018

PT. Musim Mas (Oleochemical Division)
JL. Oleo, Kawsan Industri Medan II Saentis
Percut Sei Tuan, Deli Serdang
Medan , 20371
INDONESIA

The following products sold by PT. Musim Mas (Oleochemical Division) are certified Kosher with the listed restrictions.

Name	K-ID	Status		Restriction	Size
Mascol 80	ZKR-VKXK	Pareve	Passover	BULK TRANSPORT	Tankers

Note: Transport requires separate certification, except when transported in Flexibags.

This certificate is VALID UNTIL February 28, 2019

Verify authenticity by entering K-ID at www.digitalkosher.com

Powered by: KID
DIGITALKOSHER.COM

RABBI DON YOEL LEVY, Kashruth Administrator

391 Troy Avenue, Brooklyn, New York 11213 U.S.A. • Tel: 718-756-7500 Fax: 718-756-7503 • E-Mail: info@ok.org

Certificate MY05/0006

The management system of

PT Musim Mas

Jalan Oleo, Kawasan Industri Medan II
Saentis-Percut Sei Tuan
Deli Serdang-20371, Medan
INDONESIA

has been assessed and certified as meeting the requirements of

GMP Codex Alimentarius

Recommended International Code of Practice
General Principles of Food Hygiene - CAC/RCP-1-1969, Rev. 4(2003)

For the following activities

Manufacturing of Oleochemicals Products such as Soap Noodles, Soap Bars, Amides, Esters, Fatty Alcohols, and Methylesters

Further clarifications regarding the scope of this certificate and the applicability of GMP requirements may be obtained by consulting the organisation

This certificate is valid from 22 August 2017 until 21 August 2020 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 09 June 2020
Issue 8. Certified since 10 August 2005

Authorised by

SGS (Malaysia) Sdn Bhd
Unit 10-1, 10th Floor, Bangunan Malaysian RE, No. 17, Lorong Dungun
Damansara Heights 50490 Kuala Lumpur, MALAYSIA
t 603 – 2095 9200 f 603 – 2093 8202 www.sgs.com

Page 1 of 1

Komite Akreditasi Nasional

Signatory of APLAC MRA and ILAC MRA

CERTIFICATE OF ACCREDITATION

LP-668-IDN

Date of issue : 5 September 2016

Date of expiry : 4 September 2020

Granted to

Analytical Laboratory of Oleochemicals and Speciality Fats Complex
KIM 2 - PT Musim Mas

at

Jl. Oleo, Kawasan Industri Medan II Saentis-Percut Sei Tuan, Deli Serdang, Medan 20371-Indonesia

which has shown its competence as
TESTING LABORATORY
by implementing consistently

SNI ISO/IEC 17025:2008 (ISO/IEC 17025:2005)
General Requirements for the Competence of Testing and Calibration Laboratories

for the scope of accreditation as specified in the annex
Komite Akreditasi Nasional

Prof. Dr. Bambang Prasetya
Chairman

This certificate entitles the laboratory to use the Mark illustrated herein on issued certificates/reports, letter heads, advertisement and other promotion purposes in accordance with determined regulation.

Certificate SG12/03970

The management system of

PT Musim Mas

KM 1: JL. Pulau Palu, Kawasan Industri Medan 1
Mabar, Medan 20252, Sumatera Utara
INDONESIA

has been assessed and certified as meeting the requirements of

ISO 14001:2004

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 28 May 2015 until 27 May 2018 and
remains valid subject to satisfactory surveillance audits.
Re certification audit due before 15 March 2018
Issue 2. Certified since 28 May 2012

This is a multi-site certification
Additional site details are listed on the subsequent page

Authorised by

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS EMS 04 0714 V2

Page 1 of 2

Certificate SG12/03970, continued

PT Musim Mas

ISO 14001:2004

Issue 2

Detailed scope

- **KIM I – Production, Storage & Delivery of Crude Palm Kernel Oil (CPKO), Crude Palm Kernel Olein (CPKOL), Crude Palm Kernel Stearin (CPKST) and Palm Kernel Expeller (PKE) products**
- **KIM II – Manufacturing of Oleochemicals (such as Fatty Acids, Glycerine, Soap Noodles, Soap Bars, Amides, Esters, Fatty Alcohols, Methyl Esters), Specialty Fats and Vegetable Oil Products.**
- **Belawan – Production of Refined Oils from CPO & CPKO, Storage & Delivery of Refined Oils & Oleochemicals**

Additional facilities

KIM II: JL. Oleo, Kawasan Industri Medan II, Saentis
- Percut Sei Tuan, Deli Serdang, Medan 20371
INDONESIA

JL. Pulau Nias Selatan, Kawasan Industri Medan II, Saentis
– Percut Sei Tuan, Deli Serdang Medan, 20371
INDONESIA

Belawan: Jl. Sulawesi II, Kawasan Pelabuhan Ujung Baru Belawan
Belawan I - Medan 20411
INDONESIA

UKAS
MANAGEMENT
SYSTEMS
0005

Page 2 of 2

Certificate MY12/00932

The management system of

PT Musim Mas

KIM 1: JL. Pulau Palu, Kawasan Industri Medan 1
Mabar, Medan 20252, Sumatera Utara
INDONESIA

has been assessed and certified as meeting the requirements of

OHSAS 18001:2007

Occupational Safety and Health Management Systems

For the following activities

The scope of registration appears on page 2 of this certificate.

Further clarifications regarding the scope of this certificate and the applicability of OHSAS 18001:2007 requirements may be obtained by consulting the organization

This certificate is valid from 28 May 2015 until 27 May 2018 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 15 March 2018
Issue 2. Certified since 28 May 2012

This is a multi-site certification
Additional site details are listed on the subsequent page

Authorised by

SGS (Malaysia) Sdn Bhd Systems & Services Certification
Unit 10-1, 10th Floor, Bangunan Malaysian RE, No. 17, Lorong Dungun
Damansara Heights, 50490 Kuala Lumpur, MALAYSIA
t 603 – 2095 9200 f 603 – 2093 8202 www.sgs.com

MS ISO IEC 17021:2011
OSH 1807 2007 CB 02

Page 1 of 2

Certificate MY12/00932, continued

PT Musim Mas

OHSAS 18001:2007

Issue 2

Detailed scope

- **KIM I – Production, Storage & Delivery of Crude Palm Kernel Oil (CPKO), Crude Palm Kernel Olein (CPKOL), Crude Palm Kernel Stearin (CPKST) and Palm Kernel Expeller (PKE) products**
- **KIM II – Manufacturing of Oleochemicals (such as Fatty Acids, Glycerine, Soap Noodles, Soap Bars, Amides, Esters, Fatty Alcohols, Methyl Esters), Specialty Fats and Vegetable Oil Products.**
- **Belawan – Production of Refined Oils from CPO & CPKO, Storage & Delivery of Refined Oils & Oleochemicals**

Further clarifications regarding the scope of this certificate and the applicability of OHSAS 18001:2007 requirements may be obtained by consulting the organization

Additional facilities

KIM II: JL. Oleo, Kawasan Industri Medan II, Saentis
- Percut Sei Tuan, Deli Serdang, Medan 20371
INDONESIA

JL. Pulau Nias Selatan, Kawasan Industri Medan II, Saentis
- Percut Sei Tuan, Deli Serdang Medan 20371
INDONESIA

Belawan: Jl. Sulawesi II, Kawasan Pelabuhan Ujung Baru Belawan
Belawan I - Medan 20411
INDONESIA

MS ISO/IEC 17021:2011
OSH 1807 2007 CB 02

Page 2 of 2

Certificate MY04/00044

The management system of

PT Musim Mas

Jalan Oleo, Kawasan Industri Medan II
Saentis-Percut Sei Tuan, Deli Serdang-20371, Medan
INDONESIA

has been assessed and certified as meeting the requirements of

ISO 9001:2008

For the following activities

1) Manufacturing of Oleochemical Products such as Fatty Acids, Glycerine, Soap Noodles, Soap Bars, Amides, MCT & Esters, Fatty Alcohols & Methylesters
2) Manufacturing of Specialty Fats and Vegetable Oil Products by one or more of the following process: Physical Refining, Fractionation, Neutralization, Hydrogenation, Blending, Texturing, Interesterification, Distillation, Spray Drying, Spray Cooling, Polishing, Packaging & Storage
3) Manufacturing & Packing of Emulsifiers
4) Manufacturing of HDPE Drums
5) Manufacturing of Tea-Light Candle

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2008 requirements may be obtained by consulting the organisation

This certificate is valid from 18 June 2016 until 14 September 2018 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 14 August 2018
Issue 12. Certified since 18 June 2004

Authorised by

SGS United Kingdom Ltd Certification and Business Enhancement
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 9001-8 01 0216

Page 1 of 1

MUSIM MAS

Factory:
Jl. Oleo, Kawasan Industri Medan II Saentis
Percut Sei Tuan, Deli Serdang - Medan 20371 - Indonesia
Tel: (62) 61 687 1123, Fax: (62) 61 687 1152 - 61 687 1153
Email: oleo@musimmas.com

A member of Musim Mas Group
www.musimmas.com

PT Musim Mas
Head Office: Jl. K.L. Yos Sudarso Km 7,8 Tanjung Mulia - Medan 20241 - Sumatera Utara - Indonesia
Tel: (62) 61 661 5511 - 61 661 9856, Fax: (62) 61 661 3060 - 61 661 7386

Date: 26th October 2017
Without prejudice

MASCOL 80 DECLARATION LETTER

This is to certify that MASCOL 80 manufactured by PT. Musim Mas at its Kawasan Industri Medan II (KIM II) site is derived from natural source (Palm oil) and it can replace synthetic fatty alcohol as per US FDA Title 21 : Food and Drugs, sec. 172.864 - Synthetic Fatty Alcohol.

Certified by: PT. Musim Mas	Approved by:
Eng Bung Kiang QA Manager	Wong Fok Yee Wong FG Senior GM - Oleochemicals

Disclaimer

The release of this Declaration Letter to you is subject to the disclaimers herein. The information about the products produced by us as stated in this Declaration Letter has been prepared to the best of the knowledge available to us. No representation, warranty or guarantee is given as to the accuracy of any statement or information in the Declaration Letter. You shall be responsible to ensure the use of the Declaration Letter does not contravene any laws in your jurisdiction. Accordingly, we disclaim all liability for any loss, injury or damage which may result from any use by you of the Declaration Letter to the fullest extent permitted by the law.

Factory:
Jl. Oleo, Kawasan Industri Medan II Saentis
Percut Sei Tuan, Deli Serdang - Medan 20371 - Indonesia
Tel: (62) 61 687 1123, Fax: (62) 61 687 1152 - 61 687 1153
Email: oleo@musimmas.com

A member of Musim Mas Group
www.musimmas.com

PT Musim Mas
Head Office: Jl. K.L. Yos Sudarso Km 7,8 Tanjung Mulia - Medan 20241 - Sumatera Utara - Indonesia
Tel: (62) 61 661 5511 - 61 661 9866, Fax: (62) 61 661 3060 - 61 661 7386

Date: 26th October 2017
Without prejudice

MASCOL 80 SAFER CHEMICAL DECLARATION LETTER

This is to certify that MASCOL 80 manufactured by PT. Musim Mas is currently listed in EPA (United States Environmental Protection Agency) Safer Chemical Ingredients List.

Certified by:
PT. Musim Mas

Eng Bung Kiang
QA Manager

Approved by:

Wong EG
Senior GM - Oleochemicals

Disclaimer
The release of this Declaration Letter to you is subject to the disclaimers herein. The information about the products produced by us as stated in this Declaration Letter has been prepared to the best of the knowledge available to us. No representation, warranty or guarantee is given as to the accuracy of any statement or information in the Declaration Letter. You shall be responsible to ensure the use of the Declaration Letter does not contravene any laws in your jurisdiction. Accordingly, we disclaim all liability for any loss, injury or damage which may result from any use by you of the Declaration Letter to the fullest extent permitted by the law.

MUSIM MAS

Factory:
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Tel. (62) 61 687 1123, Fax. (62) 61 687 1152 - 61 687 1153
Email: oleo@musimmas.com

A member of Musim Mas Group
www.musimmas.com

PT Musim Mas
Head Office: Jl. K.L. Yos Sudarso Km 7.8 Tanjung Mulia - Medan 20241 - Sumatera Utara - Indonesia
Tel. (62) 61 661 5511 - 61 661 9066, Fax. (62) 61 661 3060 - 61 661 7386

Date: 07 February 2018
Without prejudice

To whom it may concern:

DERIVATIVE DECLARATION LETTER

Based on our knowledge of the production methods and product formulation, Mascol 80 manufactured by PT. Musim Mas is derived from palm kernel oil.

Certified by: PT. Musim Mas	Approved by:
Eng Bung Kiang QA Manager	Wong Fok Gee Senior GM - Oleochemicals

Disclaimer

The release of this Declaration Letter to you is subject to the disclaimers herein. The information about the products produced by us as stated in this Declaration Letter has been prepared to the best of the knowledge available to us. No representation, warranty or guarantee is given as to the accuracy of any statement or information in the Declaration Letter. You shall be responsible to ensure the use of the Declaration Letter does not contravene any laws in your jurisdiction. Accordingly, we disclaim all liability for any loss, injury or damage which may result from any use by you of the Declaration Letter to the fullest extent permitted by the law.

ITEM B.6 Ancillary Substances:

NONE

ITEM B.7 Previous reviews:

The information provided by Industry Experts OMRI Reviews & Industry Certifications concerns the debate on whether the naturally derived fatty alcohol (Mascol 80) from the natural sources of palm oil, coconut oil, etc., are considered natural alcohols. Apparently OMRI's classification would depend on the review the specific ingredients and manufacturing processes to be sure about the classification as a synthetic or natural alcohol. We believe that an alcohol derived from natural plant sources should be classified as a natural alcohol as does Franco X. Milani, Assistant Professor, Extension Food Manufacturing Specialist, University of Wisconsin and Dr. James K. Whitesell, Professor of Organic and Materials Chemistry, University of California, San Diego as follows.

THE UNIVERSITY
of
WISCONSIN
MADISON

August 30, 2012

Mr. Thomas B. Harding, Jr.
AgriSystems International
125 W. Seventh Street
Wind Gap, PA 18091

Re: Independent third-party review of O-TAC agent (AKA Mascol 80, fatty alcohol methyl esters)

This document outlines the production fatty alcohol methyl esters and the similarities with natural processing found in microbiological fermentation. The rationale is to show the chemical modifications, as outlined in the fatty alcohol methyl esters process, produce the same compounds as found in fermentation processes. Fermentation is considered by many agencies to be a natural process. Benefits of the fatty alcohol methyl esters process provide for more specific chemical specie, better yields, and with substantially less collateral waste as compared to fermentation.

In the strictest sense, any chemical modification could be considered synthetic. Even something as simple as leaving naturally occurring and extracted compounds exposed to air could produce oxides that would potentially change the function of the material. However, in this case, the reductive environment is more similar to processes found in nature than a true synthetic hydrogenation. One example is the instance of natural acidification through fermentation, for example, the production of an organic acid when another organic substrate is metabolized. These are chemical changes, yet, it is widely accepted that it is also a natural process. This results in one of the most simplest chemical modification reactions: the addition of ionic hydrogen (H+) to the organic acid (COO-) to produce the protonated form of the acid (COOH). Also, once these acids are produced, they are free to react with alcohols to form esters, thus producing many of the "fruity" favors we see with fermentation (wine, cheese, beer, etc). Another well-known product of fermentation is ethyl alcohol, as well as many other alcohols. Levels of ethanol produced by yeast can get as high as 20% as seen in some biofuel applications. Alcohol production in fermentation systems is used to shuttle and store electrons to extend as much as possible the oxidation requirements of the organism's metabolism.

The fatty alcohol methyl esters process outlined produce compounds that are found in nature and are also produced in large amounts within a fermentation process. However, fermentation may have low yields and thus the fatty alcohol methyl esters process employed uses modern chemistry to produce something that could be created by natural processes, but in a way that is more economical and potentially less impactful to the environment. It is also interesting to note in fermentation systems the lack of report relative to reduction of unsaturated double bonds on the fatty acids, which is in contrast to well known and well accepted synthetic position in the hydrogenation process used with margarine manufacture.

There can be comparison of a fermentation process versus the fatty alcohol methyl esters process. Fermentation could be set up to produce free fatty acids from the plant-sourced triglycerides. Also, fermentation could also lower the oxygen content such to produce a very low oxidation-reduction potential, that is, favoring the reduction of oxygen containing compounds. This would promote the reduction of acid to the alcohol. Also, fermentation could produce methanol. The production of esters from acids and alcohols is very common in fermentation as well. The outlined fatty alcohol methyl esters process does not use fermentation, so the use of hydrogen provides for a reduced oxygen-limited environment. In biogas reactors (a specific type of fermentation), hydrogen is produced as well.

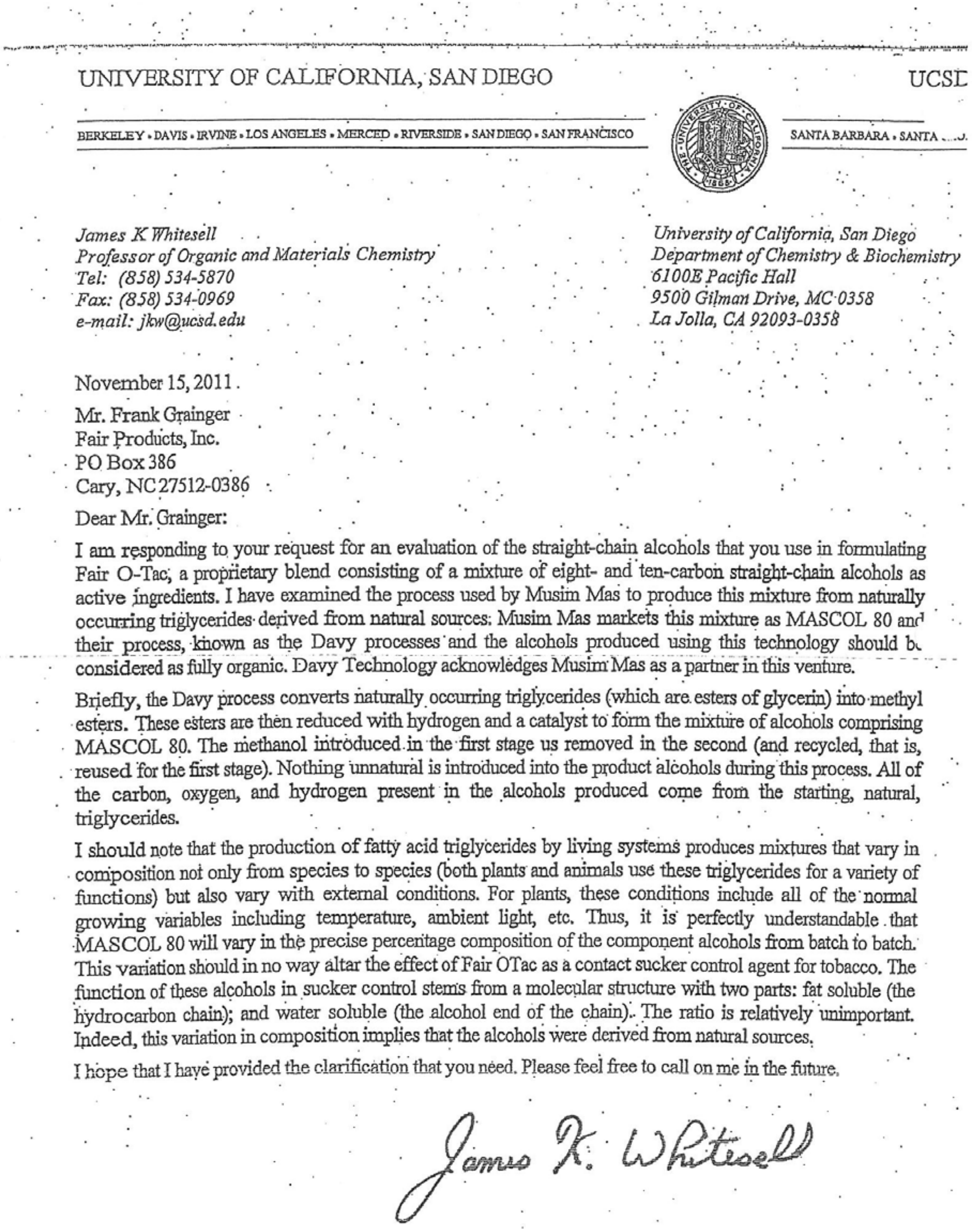
Fermentation systems have the benefit of bacterial enzymes that catalyze reactions. The benefit of using enzymes is that specific chemical modifications can be done at biological appropriate temperatures. The used of a catalyst in the fatty alcohol methyl esters process promotes the reduction of the acids, but does not get added or consumed into the chemical reaction. Just like fermentation uses moderate temperatures, the use of the catalyst in the fatty alcohol methyl esters process also allows lower temperatures to control better compounds produced. There is also only about 1 atmosphere of pressure used, just enough to help the efficiency, so again, mild conditions are employed when compared to other industries.

In conclusion, it is my opinion after reviewing the Mascol 80/fatty alcohol methyl esterification and reduction process flow, that this is more similar to a natural alcohol (green chemistry) process than a truly synthetic process.

Franco X. Milani

Franco X. Milani
Assistant Professor, Extension Food Manufacturing Specialist

Department of Food Science
University of Wisconsin-Madison
Madison, Wisconsin 53706
Tel: 608-8902640
Fax: 608-262-6872
Email: milani@wisc.edu



UNIVERSITY OF CALIFORNIA, SAN DIEGO UCSI

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO SANTA BARBARA • SANTA

James K Whitesell
Professor of Organic and Materials Chemistry
Tel: (858) 534-5870
Fax: (858) 534-0969
e-mail: jkw@ucsd.edu

University of California, San Diego
Department of Chemistry & Biochemistry
6100E Pacific Hall
9500 Gilman Drive, MC 0358
La Jolla, CA 92093-0358

November 15, 2011

Mr. Frank Grainger
Fair Products, Inc.
PO Box 386
Cary, NC 27512-0386

Dear Mr. Grainger:

I am responding to your request for an evaluation of the straight-chain alcohols that you use in formulating Fair O-Tac, a proprietary blend consisting of a mixture of eight- and ten-carbon straight-chain alcohols as active ingredients. I have examined the process used by Musim Mas to produce this mixture from naturally occurring triglycerides derived from natural sources. Musim Mas markets this mixture as MASCOL 80 an their process, known as the Davy processes and the alcohols produced using this technology should b considered as fully organic. Davy Technology acknowledges Musim Mas as a partner in this venture.

Briefly, the Davy process converts naturally occurring triglycerides (which are esters of glycerin) into methyl esters. These esters are then reduced with hydrogen and a catalyst to form the mixture of alcohols comprising MASCOL 80. The methanol introduced in the first stage us removed in the second (and recycled, that is, reused for the first stage). Nothing unnatural is introduced into the product alcohols during this process. All of the carbon, oxygen, and hydrogen present in the alcohols produced come from the starting, natural, triglycerides.

I should note that the production of fatty acid triglycerides by living systems produces mixtures that vary in composition not only from species to species (both plants and animals use these triglycerides for a variety of functions) but also vary with external conditions. For plants, these conditions include all of the normal growing variables including temperature, ambient light, etc. Thus, it is perfectly understandable that MASCOL 80 will vary in the precise percentage composition of the component alcohols from batch to batch. This variation should in no way altar the effect of Fair OTac as a contact sucker control agent for tobacco. The function of these alcohols in sucker control stems from a molecular structure with two parts: fat soluble (the hydrocarbon chain); and water soluble (the alcohol end of the chain). The ratio is relatively unimportant. Indeed, this variation in composition implies that the alcohols were derived from natural sources.

I hope that I have provided the clarification that you need. Please feel free to call on me in the future.

James K. Whitesell

<u>Previous Review NOSB “Continued”</u>

With regard to providing further information addressing the NOSB’s rejection stating “the NOSB has determined that the use of synthetic growth regulator is not compatible with a system of sustainable and organic agriculture.” This is a statement by NOSB without any rationale for such statement. Our response to this statement is as follows: “with respect to compatibility to sustainable agriculture, which is in its simplest terms is the production of food, fiber or other plant or animal products using farming techniques that protect the environment, public health, human communities, and animal welfare, we contend that the use of our product on organic tobacco is compatible with this concept.” Further, “since the natural source (palm oil) is certified sustainable, then this fact should support that fatty alcohol derived from palm oil should be judged as sustainable.” Also, “the fatty alcohol for the product O-TAC is derived from a natural (not synthetic) source-palm oil and palm kernel oil. So, we contend that this naturally derived fatty alcohol product is compatible with organic agriculture, particularly organic tobacco culture.” It should be further pointed out that in the letter included below from the Quality Certification Services (QCS) of October 17, 2017, addressing the subject “Fall 2017 NOSB Public Meeting- Public Comments it was stated that “To say that fatty alcohols are not compatible with a system of sustainable agriculture is a contradiction of the committee’s previous and current positions on similar products.” And further, “The NOSB should consider the reasons why the crops subcommittee believes fatty alcohols are not consistent with organic agriculture despite minute adverse impacts and the lack of alternative materials to meet the economical production realities and needs of organic tobacco farmers. We urge the NOSB to vote in favor of the addition of fatty alcohol 205.601 (k).”

Quality Certification Services (QCS)
PO Box 12311 Gainesville FL 32604
phone 352.377.0133 / fax 352.377.8363
www.qcsinfo.org

October 11, 2017

Ms. Michelle Arsenault, Advisory Committee Specialist
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. SW.
Room 2642-S, Mail Stop 0268
Washington, DC 20250-0268

Docket ID: AMS-NOP-17-0024
Agency: Agricultural Marketing Service (AMS)
Parent Agency: Department of Agriculture (USDA)
Subject: Fall 2017 NOSB Public Meeting – Public comments

Dear Ms. Arsenault and members of the National Organic Standards Board,

Quality Certification Services is an accredited organic certifying agent of the United States Department of Agriculture (USDA) and certifies over 1,400 operations to the USDA National Organic Program. Thank you for this opportunity to provide comments pertaining to the Fall 2017 public meeting of the National Organic Standards Board.

Crop Subcommittee Petitioned Material Proposal – Fatty Alcohols (Octanol/Decanol mix)
August 1, 2017

We urge the NOSB to reevaluate the Crops Subcommittee's reasoning for voting against the addition of fatty alcohols at §205.601(k)(2). The NOSB Crops Subcommittee provided insufficient justification for its position that the use of fatty alcohols as a growth regulator is not compatible with a system of sustainable and organic agriculture. The technical evaluation report indicates that fatty alcohols do in fact meet The Organic Food Production Act's criteria for use in organic production at section 6517 National List, specifically:

- The technical evaluation report determined that fatty alcohols would not be harmful to human health or the environment. The technical report stated "There appears to be no known detrimental chemical interactions between fatty alcohols and other materials used in organic farming systems." It goes on to describe toxicity as "moderately low," and indicates that fatty alcohols "are expected to be of low concern for environmental contamination." Furthermore, it finds that "there is no evidence to suggest that the aliphatic alcohols cause increased susceptibility to health problems in infants and children." It also explains that "no readily observable effects occur in the agroecosystem," that fatty alcohols "are known for their high level of biodegradability in the environment" and that their derivative products "are not considered endocrine disruptors."
- The technical evaluation report also showed that fatty alcohols are necessary to organic tobacco production because natural substitute products are unavailable. The only alternative identified in the report was physical topping. We would like to point out that topping is not an alternative

to fatty alcohol, as topping serves a different purpose. Fatty alcohol is used for sucker control. Topping, on the other hand, serves to minimize flowering and reduce aphid pressure by toughening plant stems. Vegetable oil, the nonsynthetic alternative to fatty alcohol, is not very effective and may damage soil. It is important to recognize the financial impact that organic tobacco production has on some of the most economically depressed regions of the country. These farmers are finding a way to keep their farms and produce their crops sustainably in a region where there is little economic development opportunity, and long distances to substantial market bases for alternative organic crops. To expect those farmers to rely solely on physical methods to control suckers while allowing synthetic substances to be used in other aspects of organic crop production where there are no natural alternatives appears to be an unfair bias against the crop and its producers.

- The proposal states the "The Crops Subcommittee does not think that the use of a synthetic growth regulator is compatible with a system of sustainable and organic agriculture." This is not consistent with other NOSB determinations. Ethylene gas is already listed as a synthetic growth regulator at §205.601(k). Additionally, §205.601 includes other synthetic materials that are not specified at OFPA Section 6517 National List (b)(1), including biodegradeable biobased mulch film, boric acid, sucrose octanoate esters, aqueous potassium silicate, peracetic acid, potassium bicarbonate, humic acids, lignin sulfonate, and ethylene gas. In fact, the NOSB Crops Subcommittee voted against removing biodegradeable biobased mulch film, boric acid, and humic acid from §205.601 in the 2019 Sunset Review. To say that fatty alcohols are not compatible with a system of sustainable and organic agriculture is a contradiction of the committee's previous and current positions on similar materials.

The NOSB should consider the reason(s) why the crops subcommittee believes fatty alcohols are not consistent with organic agriculture despite minute adverse impacts and the lack of alternative materials to meet the economical production realities and needs of organic tobacco farmers. We urge the NOSB to vote in favor of the addition of fatty alcohol at §205.601(k).

Previous Reviews NOSB Continued

Furthermore, in the sixteen page Technical Evaluation Report by the NOSB, this particular point was not addressed with any explanation by the NOSB Crops Subcommittee as to their rationale of why fatty alcohols were determined to be incompatible with a system of sustainable and organic agriculture. In fact, this Technical Evaluation Report was otherwise quite thorough and positive for the use, safety, environmental impact and support of fatty alcohols in tobacco production.

While the NOSB vote for classification was to classify fatty alcohols as synthetic, this is true for most fatty alcohols that are derived from petroleum synthesis. However, the fatty alcohol for the product O-TAC is derived from a natural (not synthetic) source – palm oil and palm kernel oil. So, we contend that this naturally derived fatty alcohol product is compatible with organic agriculture, particularly organic tobacco culture.

See copy of the “Technical Evaluation Report” below:

EPA Green List
FDA food additive
inert

submission ownership?

Fatty Alcohols (Octanol and Decanol)

Crops

Identification of Petitioned Substance: Fatty Alcohols

Chemical Names:

Fatty Alcohols (54.5% Decanol, 45.1% Octanol, 0.4% Hexanol); octan-1-ol; decan-1-ol

Other Name: Octyl-Decyl Alcohol, 1-Octanol, 1 Octanol, Alcohol, n-Octyl, n Octanol, n Octyl Alcohol, n-Octanol, n-Octyl Alcohol, 1-decanol; n-decanol; n-decyl alcohol; n-decyl alcohol, aluminum salt; n-decyl alcohol, magnesium salt; n-decyl alcohol, sodium salt; n-decyl alcohol, titanium salt

FAIR TAC
OFF-SHOOT-T
FAIR 85
add ROYAL TAC
N-TAC

Trade Names:

Kleen-tac 85, O-Tac, Green Tac, Ten-Tac, Sucker-Plucker, Alfol 80, and others. alfol 810

CAS Numbers:

68603-15-6; 112-30-1; 66455-17-2; 85566-12-7 - C8 C10

C9C11

Other Codes: decanol C8C10

111-87-5 - octanol

Octanol: InChI=1S/C8H18O/c1-2-3-4-5-6-7-8-9/h9H,2-8H2,1H3; InChI Key=KBPLFHHGFOOTCA-UHFFFAOYSA-N; Canonical SMILES=CCCCCCCCO; EC Number= 203-917-6, 271-642-9, 606-925-1; ICSC Number=1030, 1170; RTECS Number=RH6550000, RH795000; UNII=NV1779205D;

Decanol: InChI= 1S/C10H22O/c1-2-3-4-5-6-7-8-9-10-11/h11H,2-10H2,1H3; InChI Key= MWKFXSUHUHTGQN-UHFFFAOYSA-N; Canonical SMILES= CCCCCCCCCCO; EC Number= 203-956-9, 266-367-6, 253-173-1, 287-621-2, 613-644-8; ICSC Number=1490; RTECS Number=HE4375000; UN Number=3082, 1987; UNII=89V4LX79

Summary of Petitioned Use

A petition was received by the National Organic Program to add Fatty alcohols, a mixture of aliphatic alcohols, hexanol, octanol and decanol to the National list 7 CFR 205.601 (k) under the heading plant growth regulator. The petitioned use for a mixture of fatty alcohols, consisting mainly of octanol and decanol, is topping and sucker control on organic crops.

Characterization of Petitioned Substance

Composition of the Substance:

Monohydric aliphatic alcohols containing six to ten carbons are called lower alcohols. Those containing twelve to twenty carbons are called higher alcohols (Atwood, 1963). Historically, lower and higher alcohols were derived from natural fats, oils and waxes hence the name fatty alcohols. Now a similar mixture of fatty alcohols that is synthetically produced from petrochemical feedstocks, is widely available (NPCS Board of Consultants & Engineers, 2010). The C_6-C_{12} linear alcohols are used for plasticizers, surfactants, tobacco sucker control, mining chemicals and in the manufacture of fatty amines.

ALFOL 810 Alcohol, a product containing C_6-C_{12} linear alcohols was the first mixed fatty alcohol product registered with the Environmental Protection Agency as a tobacco topping and suckering agent. It was registered by the Continental Oil Company under EPA reg. no. 39496-1. ALFOL 810 has the same composition as Mascol-80 which is referenced in the petition with EPA registration number 63896-1 (Table 1).

The Alfol process to produce fatty alcohols combines aluminum, ethylene, hydrogen and air to synthetically produce a mixture of lower and higher alcohols (Atwood, 1963). However, sufficient quantities of plant derived raw materials (e.g. palm kernel oil) for this product are available. The Davy process is used to produce fatty alcohol from vegetable oils. Fair products, Inc., mentioned in this petition, and the Drexel Chemical Company currently market fatty alcohols for tobacco sucker control. Drexel's tobacco sucker control agent is called "Sucker-Plucker." It contains 85% active ingredients (fatty alcohols) and 15% non-active ingredients. The non-active label ingredient polysorbate-80 (tween-20) is a surfactant essential to the effectiveness of the fatty alcohols (Tso et al.,

Tween 80

1975). The EPA registration number for this product is 19713-35 (Table 1). It is derived from a fatty alcohol mixture typically containing C_6 0.5%, C_8 42.0%, C_{10} 56% and C_{12} 1.5% linear alcohols (EPA, 1993, 2004, 2011). A similar product to "Sucker-Plucker" from Fair products, Inc. is cited in this petition as O-TAC Plant contact agent (EPA reg. no. 51873-18) containing 36.2% Octanol, 48.2% decanol and 0.3% dodecanol (Table 1). O-TAC is currently described as a plant control agent for organic, purity residue clean (PRC) and maleic hydrazide free tobacco. Table 1 provides information about several fatty alcohol products for tobacco topping and suckering.

Table 1 Fatty Alcohol Products for Tobacco Topping and Suckering

Fatty Alcohol Product Name	Composition on EPA registered Label (percent)				EPA Registration Number
	C_6	C_8	C_{10}	C_{12}	
ALFOL 810	≤ 1	39-47	51-59	≤ 1	39496-1
Mascol-80	-	45.1	54.5	-	63896-1
Sucker-Plucker	0.5	42.0	48.2	0.3	19713-35
O-TAC	-	36.2	48.2	-	51873-18
N-TAC		45	55		51873-18

7/18/13 registration number become 51873-20

Source or Origin of the Substance:

Petroleum derived feedstocks are the primary source material for synthetically produced medium chain length lower and higher alcohols. However, palm, palm kernel and coconut oils are also available sources for producing fatty alcohols in the C_8-C_{14} chain lengths (Reck, 1985). Because of the importance of fatty alcohols in many industries, there is significant ongoing research in producing medium chain length fatty alcohols via fermentation in yeast or bacteria, i.e. enzymatic reduction of fatty acids. Although reports have shown positive findings, this production route is not yet available commercially. Therefore, naturally produced fatty alcohols are not yet available in sufficient quantities for commercial use as topping and suckering agents (Wang, 2016).

Properties of the Substance:

Fatty alcohols produced from palm oil, palm kernel oil and coconut oil by the Davy process for use as tobacco suckering agents are aliphatic alcohols with six to twelve carbons; however the most abundantly produced fatty alcohols in this mixture are caproic alcohol, caprylic alcohol, and capric alcohol (Tables 2, 3, Fig. 1). The primary alcohols exhibit some trends. For example, for each additional $-CH_2-$ unit the normal boiling point increases about 20°C, the specific gravity increases 0.003 units and the melting point increases about 10°C in the lower range and about 4°C in the higher range. Water solubility decreases and oil solubility increases with increasing molecular weight. The fatty alcohols are all liquid with light natural fruity odors (NPCS, 2010). Both the density and viscosity of fatty alcohols increase with increasing molecular weight (Rauf et al., 1983).

Specific Uses of the Substance:

Fatty alcohols, octanol and decanol are used to chemically remove flower buds and suckers from tobacco plants. Removal of the flower tops and the suckers encourages the growth of larger leaves. The use of fatty alcohols is an alternative to two laborious hand operations in tobacco production. Topping or removal of buds or flowers and subsequent removal of suckers (lower leaves) by hand requires ten or more hours per acre. A course spray of 5% decanol or a combination of decanol and octanol applied before bud formation inhibits the formation of the bud. Fatty alcohol dripping down the stem of the plant inhibits sucker formation. Yields are also increased with the use of this treatment (USDA-ARS, 1970).

Table 2 Physical properties of the low molecular weight fatty alcohols*

IUPAC name	Common name	CAS registry number	Molecular formula	MW	Hydroxyl number	Melting point, °C	Boiling point,°C (p.kPa)
1-Hexanol	Caproic alcohol	111-27-3	$C_6H_{14}O$	102.2	548	-52	157
1-Heptanol	Enanthic alcohol	111-70-6	$C_7H_{16}O$	116.2	482	-30	176
1-Octanol	Caprylic alcohol	111-87-5	$C_8H_{18}O$	130.2	430	-16	195
1-Nonanol	Pelargonic alcohol	143-08-8	$C_9H_{20}O$	144.3	388	-4	213
1-Decanol	Capric alcohol	112-30-1	$C_{10}H_{22}O$	158.3	354	7	230
1-Undecanol	-	112-42-5	$C_{11}H_{24}O$	172.3	326	16	245
1-Dodecanol	Lauryl alcohol	112-53-8	$C_{12}H_{26}O$	186.3	300	23	260

from (Condea, 2000)

Approved Legal Uses of the Substance:

Fatty (aliphatic) alcohols containing a mixture of six, eight, ten and twelve carbons are approved by the US Environmental Protection Agency as the active ingredients for use as plant regulators for tobacco sucker control. Synthetic hexyl-, octyl- and decyl-alcohol maybe safely used in food and in the synthesis of food components provided that the alcohol's purity of the alcohol is 99% or greater. Synthetic fatty alcohols may only be used as substitutes for and to the extent that naturally derived fatty alcohols are found in foods (US FDA, 21 CFR §172.864). The US Department of Agriculture does not regulate the use of fatty alcohols for tobacco sucker control.

Action of the Substance:

Tobacco grades are based on the manufacturer's use for cured leaf. Grades are determined by certain physical and chemical properties. These properties are to a great extent determined by the position of the leaf on the plant. Usually leaves on the lowest part of the plant are not considered useful and removed in the suckering process (Calvert, 1956a). Tso (1964) first reported that alkyl esters of C_9 to C_{12} fatty acids inhibited the growth of axillary buds when applied to tobacco plants that had been topped (Tso et al., 1965). It was later reported that both lower alkyl esters of the C_8 to C_{12} fatty acids and the C_8 to C_{10} fatty alcohols in aqueous emulsions selectively killed the terminal meristems of a wide variety of plants without damaging the axillary meristems, foliage, or stem tissues of the plants (Cathey et al., 1966). Fatty alcohols depress the surface tension along chloroplast and mitochondrial membranes reducing phosphorylation by allowing water to leak into a hydrophobic lipid-protein environment inhibiting nicotinamide adenine dinucleotide dependent respiration (Thore and Baltscheffsky, 1965). The leakiness causes desiccation producing a burned appearance on the leaf tissue surface (Wheeler et al., 1991). Fatty alcohols with chain lengths of C_9, C_{10}, and C_{11} are better on a molar basis in selectively killing or inhibiting axillary and terminal bud growth of tobacco than the corresponding alkyl esters. Pure 1-decanol is reportedly the most effective topping and suckering agent (Steffens and McKee, 1969).

Without an appropriate surfactant both the C_9 to C_{11} methyl esters and the C_8 to C_{10} fatty alcohols exhibited nonselective tissue kill. At a concentration as low as $1.4x10^{-1}$ Molar, fatty alcohols cause immediate swelling of plant cell nuclei and a general cessation of cell division. Cells can become poly-nuclear as a result of exposure. At high concentrations fatty alcohols cause discolorization of root tips (Tso and Burk, 1969). However, with a surfactant the fatty alcohol emulsions are phytotoxic only to young meristematic tissue but caused little or no visible injury to more mature tissue (Steffens et al., 1967).

Topping and desuckering influence the yield and the quality of tobacco topping at the elongated bud stage with 16 leaves producing good yield and quality (Rao et al., 2003). The use of a 4% solution of 1-decanol applied by brushing 10 days after topping to the ten top axils of tobacco improved yield 67% over hand topping or treatments with Neem oil (Singh et al., 1998) The value of topped and suckered tobacco is higher. The use of 7.5% fatty alcohols with a surfactant improves both the price and the yield of burley tobacco. The alkaloid content in topped tobacco is higher than untopped, although total nitrogen was unchanged (Mylonas and Pangos, 1977).

If manual topping is performed on tobacco immediately after flower bud formation, manual suckering must be done frequently and regularly for the following three months as the axillary growth continues. Applying fatty alcohols as a topping agent and/or after topping can reduce the intensive labor required for topping and/or suckering (Bhat et al., 1994). Production lots of fatty alcohols contain a distribution of C_6-C_{12} chain length alcohols. The C_6 alcohols are not active suckercides. Whereas, C_8 chain length alcohol is about 50% effective. C_9, C_{10} and C_{11} chain length alcohols are 100% effective and C_{12} length alcohol is less effective. Higher chain lengths are not effective (Steffens et al., 1967). Suckering with fatty alcohols (C_6-C_{12}) generally produced a higher yield than manual suckering and does not alter USDA grading characteristics (Bruns, 1987).

Combinations of the Substance:

Tween 80

Fatty alcohols are combined with the surfactant polyoxyethylene (20) sorbitan monooleate, i.e. polysorbate 80, (tween 20). The surfactant permits an aqueous emulsion to be formed in the fatty alcohol solution, providing an even distribution of the active substance. There is clear evidence that the use of fatty alcohols for tobacco topping and suckering without a surfactant causes damage to the plant (Tso, 1964). Polysorbate 80 is a mixture of polyoxyethylene ethers of mixed partial oleic esters of sorbitol anhydrides and related compounds. It is approved by the FDA for safe use as an additive in many food applications (21 CFR §172.840).

Status

Historic Use:

Topping and suckering have been used in tobacco production for many years. Benefits include improved tobacco quality and a significant increase in tobacco yield (Hunter, 1954). Hand topping tobacco plants in late summer promotes full development of upper leaves adjacent to the terminal (flower) buds. Two weeks after topping, suckers that have subsequently developed along the stalk are also removed by hand. Suckers interfere with harvesting and curing operations. As much as ten or more hours per acre are spent on hand topping and suckering (USDA-ARS, 1970). Fatty alcohols were introduced in conventional tobacco production as chemical topping and suckering agents in the late 1960s. The use of fatty alcohols for topping and suckering also significantly increases yield (USDA-ARS, 1970).

Organic Foods Production Act, USDA Final Rule:

There is no reference in the National List for fatty alcohols. The proposal to add fatty alcohols to the National List specifies 7 CFR 205.601 (k) under the heading plant growth regulator. This section of the National List currently describes the use of the synthetic substance ethylene in organic crop production as a plant growth regulator for regulation of pineapple flowering. Fatty alcohols as aqueous emulsions inhibit terminal or axillary bud growth of tobacco plants. Contact with meristematic tissue affects plant development by preventing the growth flower buds and suckers (Tso et al., 1965; Steffens and Barer, 1984).

International

Canada - Canadian General Standards Board Permitted Substances List (CAN/CGSB-32.311-2015)

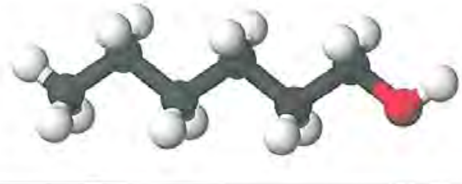
Fatty alcohols were not found in the Canadian standard (CAN/CGSB 2015).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) -

Fatty alcohols were not found in the Codex Organic guidelines (GL 32-1999).

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008

Fatty alcohols were not found in the EEC organic standards, EC No. 834/2007 and 889/2008.

Table 3 Space Filling Structure Renditions of Lower Fatty Alcohols*	
1-Hexanol	
1-Octanol	
1-Decanol	
1-Dodecanol	
*carbon=black, hydrogen=white, oxygen=red	

Japan Agricultural Standard (JAS) for Organic Production –

Fatty alcohols were not found in the MAFF organic standard.

International Federation of Organic Agriculture Movements (IFOAM) –

Fatty alcohols were not found in the IFOAM guidelines.

Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

<u>Evaluation Question #1: Indicate which category in OFPA that the substance falls under:</u> (A) Does the substance contain an active ingredient in any of the following categories: copper and sulfur compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers? (B) Is the substance a synthetic inert ingredient that is not classified by the EPA as inerts of toxicological

concern (i.e., EPA List 4 inerts) (7 U.S.C. § 6517(c)(1)(B)(ii))? Is the synthetic substance an inert ingredient which is not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part 180?

Fatty alcohols do not fall into any of the OFPA categories. Fatty alcohols produced as a mixture of four aliphatic alcohols are not considered inert by the Environmental Protection Agency nor are they included in List 4. Fatty alcohols may be registered with the EPA only for tobacco sucker control. N-decyl alcohol (decanol) and n-octyl alcohol (octanol) are individually approved by the US Food and Drug Administration (FDA) for food and non-food use as solvents or co-solvents (7 CFR §172.864 Synthetic fatty alcohols).

Evaluation Question #2: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

Fats and oils from animal and vegetable sources (oleochemical) are the primary feedstocks for manufacturing naturally sourced fatty alcohols. These feedstocks contain triglycerides composed of three fatty acids and glycerol. Alcohols are produced by esterification and/or reducing the fatty acid functional groups. Any triglyceride or fatty acid may be used as a raw material for fatty alcohol production (NCPS, 2010). The common sources are coconut oil, palm kernel oil, lard, tallow, rapeseed oil, soybean oil and corn oil. Producers of natural fatty alcohols typically make a broad range of fatty alcohol products having various carbon chain lengths. They vary feedstocks to meet market needs for particular alcohols and to take advantage of changes in the relative costs of the various feedstock material (NCPS, 2010; Reck, 1985).

There are a number of production processes for producing natural fatty alcohols. These have evolved since the 1930's to improve safety and efficiency. The earliest production began with the sodium reduction of the methyl esters from natural fats and oils. In this process molten sodium was mixed with dried ester and alcohol which acts as a hydrogen donor. Many safety precautions were necessary due to the large amount of metallic sodium used. A safer hydrogenolysis process was developed to replace the sodium reduction process. Triglycerides need to be refined to remove free fatty acids, phosphatides, sterols, and oxidation products as well as debris. This step is followed by esterification to produce fatty acid methyl esters and/or hydrogenolysis of methyl esters or fatty acids in the presence of a catalyst at high pressure and temperature to produce methanol and fatty alcohol. The final products are refined or distilled (Kreutzer, 1984).

In the Lurgi process fatty acids are first converted to wax esters and then hydrogenated over a fixed bed reactor. This differs from the Davy process since there is no conversion to methyl esters and fatty alcohols come directly from wax esters. The Lurgi process has been in commercial use since 2004. The Davy Process is used primarily for detergent alcohols with greater than 12 carbons; however, it can also be used for the production of plasticizer alcohols containing between 6 and 12 carbons. The Davy process provides an improved process for production of fatty alcohols by hydrogenation of lower alkyl esters, particularly methyl esters of fatty acids derived from natural triglycerides under conditions that minimize formation of byproduct alkanes and ethers followed by refining of the resulting ester containing product (Wilmott et al., 1992). Many production plants throughout the world have been licensed to produce fatty alcohols using the Davy process (Fig. 1).

Fatty alcohols are also produced synthetically from petroleum. Alkylaluminum derivatives are produced by adding hydrogen and ethylene to an aluminum slurry. Alkylaluminum reacts with ethylene to increase carbon chain length. Higher trialkylaluminum species produced by reacting ethylene with alkylaluminums under pressure at about 120°C can be further reacted with ethylene at higher temperatures to give straight chain alcohols with up to 22 carbons (alfene process). Reaction of the higher trialkylaluminums with air and sulfuric acid yields higher n-alcohols: alfol process (Atwood, 1963; Continental Oil, 1962; 1973). The choice of catalyst and reaction conditions significantly affect the process (Miller, 1969). For fatty alcohol production, it is difficult to practice an esterification on a continuous basis, thus it is convenient to adopt batch processing.

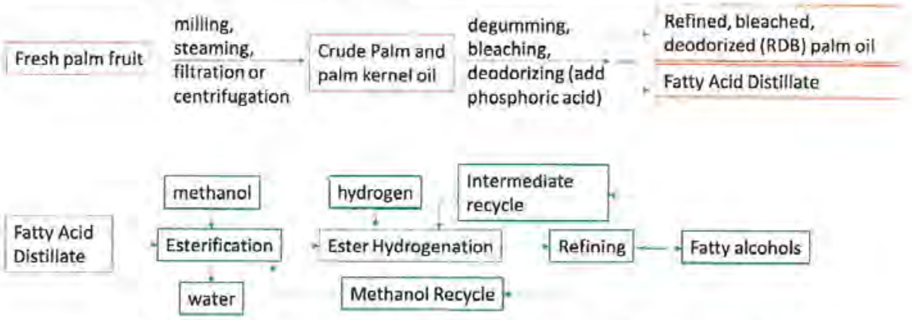


Fig. 1 Davy process for Fatty Alcohols production from olefins (Palm Oil)

Evaluation Question #3: Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)).

The present world capacity of plant derived and petroleum derived fatty alcohols is greater than two million metric tons/year. Much of this production goes in to making detergents or plastics. Petroleum derived fatty alcohols production is estimated to be just 23% of total global capacity, whereas plant derived fatty alcohols production is currently 77% of total global capacity (Oleoline, 2015). In the USA the bulk of fatty alcohols is of petrochemical origin, whereas in Europe more than 60% of the total volume is made from natural fats and oils (Kreutzer, 1984).

Fatty alcohols occur in free and esterified form in many animal and vegetable waxes. Although these waxes are normally composed of long carbon chains, 1-octanol and 1-decanol have also been found naturally in various food items (Mahadevan, 1978). The aliphatic alcohols are natural components of apples and oranges, and have been reported as a component of edible seeds, oils and fermented beverages (EPA, 2007). Aliphatic hydrocarbons can be converted to fatty alcohols by many organisms including bacteria with enzymes in the family of fatty acyl-CoA reductases (Roessler et al., 2014). Because fatty alcohols have important industrial uses as medicines, cosmetics, skin care products, detergents, fuels and plasticizers in addition to their role in tobacco production, extensive research to develop fermentation systems producing fatty alcohols has been undertaken over the past few years with the intention of industrial production in the near future (McCoy et al., 2010; Kallio et al., 2014). Naturally found strains of bacteria including *Escherichia coli*, *Salmonella spp.*, *Klebsiella spp.*, and *Enterobacter spp.* are known to excrete 1-octanol, 1-decanol and 1-dodecanol. Several, *E. coli* strains being examined for commercial scale production of 1-octanol and 1-decanol respectively produced as much as 508 and 740 nanograms/milliliter of culture (Hamilton-Kemp et al., 2005).

Mutations introduced into *Escherichia coli* strains have resulted in a number of commercially viable fermentation approaches to produce n-alcohols (Dellomonaco et al., 2011). By favoring chain elongation in an anaerobic bacterial growth rescue cycle, enzymes for the production of n-hexanol and n-octanol can be enriched increasing the production of fatty alcohols (Machado et al., 2012). High levels of fatty alcohols (> 350 milligrams/liter of culture) can be produced in *E. coli* from a class of enzymes called carboxylic acid reductases (CAR). These enzymes catalyze the reduction of aromatic and short chain carboxylic acids to their respective aldehydes in the presence of adenosine triphosphate (ATP) and nicotinamide adenine dinucleotide phosphate (Akhtar et al., 2013). Mutated *E. coli* strains that produce upwards of 6.33 grams of fatty alcohol per liter of culture support future alternative industrial fermentation methods for the production of fatty alcohols (Liu et al., 2016).

Evaluation Question #4: Describe the persistence or concentration of the petitioned substance and/or its by-products in the environment (7 U.S.C. § 6518 (m) (2)).

Alcohols with chain lengths up to C_{18} including hexanol, octanol, decanol, dodecanol, tetradecanol, hexadecanol and octadecanol are readily biodegradable within ten days. Production plant effluents often appear to only contain naturally occurring products, in spite of fatty alcohols introduced into their influents. This is because microbial action has rapidly altered the influent alcohols to naturally occurring products in the effluent (Mudge et al., 2014; Stahl and Pessen, 1953). Fatty alcohols are relatively stable with respect to abiotic degradation in water. Photo-oxidation in aqueous systems is not significant. Alcohols have no hydrolysable groups and are therefore not susceptible to hydrolysis. Fatty alcohol oxidation is expected under normal environmental conditions. The fatty alcohols are susceptible to atmospheric degradation by hydroxyl radicals, with half-lives ranging between approximately 10-30 hours. Longer chain lengths have shorter estimated half-lives within this range (OECD, 2006). Fatty alcohols are used in the manufacture of surfactants for detergents and personal care products. These products are mostly disposed of down the drain at a rate of about 185,000 metric tons per year. Most use is as laundry detergent totaling about 532,000 metric tons per year. Fatty alcohols used for detergent production are mostly sourced from petroleum products in the US. By comparison, the contribution of fatty alcohols to the environment from tobacco topping and suckering is very small (Mudge and DeLeo, 2014).

<u>Evaluation Question #5:</u> Describe the toxicity and mode of action of the substance and of its breakdown products and any contaminants. Describe the persistence and areas of concentration in the environment of the substance and its breakdown products (7 U.S.C. § 6518 (m) (2)).

The octanol-water partition (Log K_{OW}) coefficient is a laboratory measurement of the hydrophilic-lipophilic balance of a substance. It measures the tendency of a substance in the environment to prefer an organic or oily phase, e.g., fish (fat) and muscle or sediment, rather than an aqueous phase. The compound is first dissolved in water to a known concentration and placed in an octanol-water system and allowed to equilibrate. The concentration in the aqueous phase is re-determined using UV-visible light spectroscopy (Dalyrimple, 2005). The K_{OW} represents the membrane lipid-water barrier because octanol ($C_7H_{15}CH_2OH$) represents lipids in living organisms. Lipids and octanol have a similar carbon to oxygen ratio. Thus, it is used as an indicator of bioconcentration and bioaccumulation in the environment. The density, solubility and K_{ow} values for some fatty alcohols are given in Table 4. K_{ow} values are generally low for the C_6-C_{12} alcohols and increase with increasing molecular weight.

Table 4 Fatty Alcohol Density and Solubility

Name	Carbon Number	Molecular Weight, daltons	Density(d^{20}) grams/ml	Solubility @25°C-grams/liter	Log K_{ow}
Octanol	8	130.2	0.827	0.5	3.15*
Nonanol	9	144.3	0.828	0.1	3.77
Decanol	10	158.3	0.830	0.04	4.57
Undecanol	11	172.3	0.832	0.008	4.72
Dodecanol	12	186.3	0.831@24°C	0.00019	5.36

from Mudge, 2005; Fisk et al., 2009

*octanol-water partition coefficient used to measure K_{ow}

<u>Evaluation Question #6:</u> Describe any environmental contamination that could result from the petitioned substance's manufacture, use, misuse, or disposal (7 U.S.C. § 6518 (m) (3)).

The <u>Safer Chemical Ingredients List</u> (SCIL) lists chemical ingredients that EPA's Safer Choice Program has evaluated and determined to be safer than traditional chemical ingredients. This list was designed to help manufacturers find safer chemical alternatives to meet the criteria of the Safer Choice Program. Safer Choice decides to include a chemical on the SCIL based on the hazard information from a broad set of resources, including the identification and evaluation of all available toxicological and environmental fate data. According to the Safer Choice determination of the EPA, 1-decanol, 1-octanol, 1-dodecanol and the C_6-C_{12} alcohols are expected to be of low concern based on experimental and modeled data.

Linear fatty alcohols in general are easily biodegradable. The solubility of fatty alcohols in water decreases with an increasing C-chain length. Fatty alcohols possess only moderate acute toxicity for aquatic organisms. In general, in their range of water solubility no toxic effects are observed. However, a number of studies were performed with concentrations that are considerably above the water solubility. Available data for fatty alcohols chronic toxicity do not indicate a special toxicological potential (Condea, 2000).

Fatty alcohols are recognized as High Production Volume (HPV) chemicals. Global production volume is estimated at over 1.9 million metric tons. Linear to slightly branched log chain alcohols ranging from 6 to 22 alkyl carbons (C) biodegrade exceptionally rapidly in the environment (half-lives on the order of minutes); however, due to continuous use and distribution to waste water treatment systems, partitioning properties, biodegradation of alcohol based surfactants and natural alcohol sources, linear chain alcohols are universally detected in waste water effluents. A large fraction of environmentally detected alcohols are naturally derived alcohol from animal, plant and microbiologically mediated biotransformations. The fatty alcohols from both natural and manufactured sources represent a low risk for environmental contamination (Belanger et al., 2009).

C_6-C_{12} fatty alcohols are likely to volatize quickly, however, longer chain alcohols (C>12) reaching water supplies are not expected to be hydrolytically degraded (EPA, 2007). The shorter chain fatty alcohols (C<12) are degraded by oxidation and hydrolysis (Patterson et al., 1970). In the atmosphere all C-H containing organic substances react with photochemically generated hydroxyl radicals. The half live for photodegradation of the fatty alcohols varies between 12 and 30 hours (measured for 1-hexanol). Fatty alcohols are biodegradable, and those above C_{11} may be considered potentially bioaccumulative. Alcohols act by non-polar narcosis. Any toxicity produced by the fatty alcohols with chain lengths less than 12 is considered sub-acute with a fifty percent effective concentration (EC_{50}) ranging from 2.0 to 25 milligrams/liter (Fisk et al., 2009). The category comprises a homologous series of linear and essentially linear C_6 - C_{22} alcohols. In addition catalysts such as sulfuric acid present an environmental issue (Condea, 2000).

Increasing carbon chain length leads to a predictable pattern in physico-chemical properties that drives a distinct range of fate behaviors in the environment. Fatty alcohols all have the same mode of ecotoxicological action. In addition, they are all rapidly biodegradable especially at environmentally relevant concentrations. Alcohols are metabolized/bio-transformed in living organisms suggesting that bioaccumulation potentials based on octanol-water partition coefficients are likely to be overestimated. Measured biological concentration factor (BCF) data on fatty alcohols supports the concept that the bioaccumulation potential of these substances will be lower than estimated from log K_{ow}. 1-hexanol and 1-octanol present a hazard for the environment (acute toxicity to fish, daphnids and algae in the range 1 - 100 mg/l). However, both of these substances are readily biodegradable. 1-decanol and 1-undecanol present a greater hazard for the environment (high acute toxicity to fish, daphnids and algae, in the range 0.1 - 1 mg/l, and/or high chronic toxicity). The substances in this subgroup biodegrade rapidly and environmental monitoring data from seven countries indicates exposures to the environment is anticipated to be low (OECD, 2006).

Available toxicity data indicate that aliphatic alcohols are "practically non-toxic" to honey bees (acute contact LD50 > 25 µg/bee). However, given that aliphatic alcohols can be used as Lepidopteran sex inhibitors, there is a potential for sublethal (e.g., reproductive) effects on non-target Lepidopterans, such as butterflies. This potential effect cannot be quantified at this time (EPA, 2007).

Evaluation Question #7: Describe any known chemical interactions between the petitioned substance and other substances used in organic crop or livestock production or handling. Describe any environmental or human health effects from these chemical interactions (7 U.S.C. § 6518 (m) (1)).

Manual topping and suckering is labor intensive, but does not involve the use of any chemical substance. Mineral oil, cooking oil or paraffin oil are currently the only topping and suckering substances used by organic crop producers (Little et al., 2008). Fatty alcohols are used independently of other topping and suckering chemicals. There is no known interaction between the fatty alcohols that might be used for topping and suckering (Calvert, 1953).

Evaluation Question #8: Describe any effects of the petitioned substance on biological or chemical interactions in the agro-ecosystem, including physiological effects on soil organisms (including the salt index and solubility of the soil), crops, and livestock (7 U.S.C. § 6518 (m) (5)).

Tween 80

When fatty alcohols are applied to tobacco plants for suckering with a surfactant such as tween 20, an average residue of 1.6 parts per million (ppm) of the applied fatty alcohols and 1.0 ppm of the surfactant remain on the cured leaves. Over 7000 ppm of naturally occurring fatty alcohols are also present in and on the cured leaves (Tso et al., 1975). Fatty alcohols induce a low incidence of polynucleate root tip cells or root tip cells with fragmented nuclei (Tso and Burk, 1969). The fatty alcohols are produced naturally, in all living organisms, from bacteria to man, and thus, are widely present throughout the natural world. In any agro-ecosystem, fatty alcohols will be present from natural sources. The introduction of C_6-C_{12} fatty alcohols for topping and suckering may produce short term toxicity to many organisms in the range of 1-100 milligrams/liter, however; because the application rate is intermittent and biodegradability and removal rate are high for this substance no readily observable effects occur in the agroeosytem (OECD, 2006).

Evaluation Question #9: Discuss and summarize findings on whether the use of the petitioned substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

The fatty alcohols are of ecological interest because of their widespread use as surfactants, detergents and personal care products. They are "down the drain products." In addition fatty alcohols are chemicals that naturally occur in all plants and animals. In general, fatty alcohols with carbon chains longer than C_{12} are found in the environment. Industrially derived fatty alcohols constitute less than 1% of the total amount of fatty alcohols present in the environment, based primarily on stable radioisotope labelling studies (Mudge et al., 2014).

Fatty alcohol products have been assessed for their chronic ecotoxicity in North America and Europe (Belanger et al., 2006). Statistical modelling of distributions and toxicities to algae, fish, daphnids and various controlled experimental systems has been performed and evaluated with the results refined to toxic units based model. The model indicates that the overall fatty alcohol products as a result of their high level of biodegradability and low toxic units, 0.015 to 0.212, were considered a very low risk for environmental contamination (Sanderson et al., 2013). Fatty alcohols are known for their high level of biodegradability in the environments. Their derivative products are additionally designed to rapidly degrade after use (Atkinson et al., 2009). Fatty alcohols are not considered endocrine disrupters.

Long chain alcohols (LCOH) with a carbon chain length range of C_6–C_{22} covering 30 substances, and 41.5 million metric tons/year consumed globally, were evaluated under the Organization for Economic Cooperation and Development (OECD) high production volume chemicals program in 2006. The main findings of the assessment include: (1) no unacceptable human or environmental risks were identified; (2) these materials are rapidly and readily biodegradable; (3) a parabolic relationship was demonstrated between carbon chain length and acute and chronic aquatic toxicity; (4) category-specific (quantitative) structure-activity relationships were developed enabling prediction of properties across the entire category; (5) LCOH occur naturally in the environment in an equilibrium between synthesis and degradation; (6) industry coming together and sharing resources results in minimizing the need for additional animal tests, produces cost savings, and increases scientific quality of the assessment (Sanderson et al., 2008). Daphnia, a standardized environmental test crustacean, is effected by 1-decanol at a concentration of approximately 1 milligram per liter (Schafers et al., 2009).

Fatty alcohols have a moderate tendency to bind to soils. The portion of applied chemical binding to the soil, rather than volatilizing, will be subject to biodegradation, with estimated half-lives for 1-octanol and 1-decanol of 2.3 days. The portion of applied chemical that does volatilize is estimated to degrade in the air by reaction with hydroxyl radicals with half-lives of about 10 hours (EPA, 2007).

Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

Toxicity data for the aliphatic alcohols consisting of acute toxicity, irritation, and sensitization studies, developmental rat (oral and inhalation) toxicity studies and a 90-day rat (dermal) study were evaluated for the Environmental Protection Agency (EPA) health risk determination. The available mutagenicity studies included the Ames, micronucleus, and gene mutation assays. Acute inhalation studies with the rat resulted in estimates of the median lethal dose (LD_{50}) above the limit concentration of 2 milligrams/Liter. However, eye irritation studies resulted in severe and sometimes non-reversible eye irritation. Dermal irritation studies revealed slight to moderate irritation in rabbits, and the aliphatic alcohols generally did not produce sensitization in tests with guinea pigs. There is no evidence to suggest that the aliphatic alcohols cause increased susceptibility in infants and children. Based on the results of the available studies, no endpoints of toxicological concern have been identified for human health risk assessment purposes. The EPA concluded that there are no human health risks of concern for aliphatic alcohols. Currently, there is no known mode of toxicological action for the aliphatic alcohols. Based on the low hazard concern via the oral, dermal, and inhalation routes of exposure, a quantitative risk assessment for the aliphatic alcohols was not found necessary (EPA, 2007).

EPA is updating the Restricted Entry Interval (REI) and Personal Protective Equipment (PPE) requirements for aliphatic alcohols. 1-Decanol, which is a component of all the tobacco sucker control products in this case, is an acute Toxicity Category I eye irritant; therefore, pursuant to the Worker Protection Standard (WPS) and according to the EPA Office of Pollution Prevention and Toxics (OPPTS) Label Review Manual 3rd Edition, products with agricultural uses must require a 48 hour REI and the following personal protective equipment (PPE) for early entry: coveralls, chemical-resistant gloves made of any water proof material, shoes plus socks, and protective eyewear (EPA, 2007).

Fatty alcohol products used for tobacco topping and suckering are of not very toxic following acute and repeated exposures. Although, skin and eye irritation are commonly observed. The mammalian metabolism of fatty alcohols used in tobacco topping and suckering is highly efficient. (Veenstra et al., 2009; OECD, 2006). Aliphatic alcohols are absorbed by all common routes of exposure, widely distributed within the body and efficiently eliminated. There is a limited potential for retention or bioaccumulation for the parent alcohols and their biotransformation products. Overall, toxicology databases show an inverse relationship between chain length and toxicity. The shorter chain alcohols tend to induce more pronounced effects when compared to materials with a longer chain length. This is illustrated most clearly by the degree of irritation in skin and eye irritation studies in laboratory animal studies. For the aliphatic alcohols in the range C_6 - C_{11} a potential for skin and eye irritation exists, without concerns for tissue destruction or irreversible changes. Aliphatic alcohols in the range C_{12} - C_{16} have a low degree of skin irritation potential. The eye irritation potential for alcohols with a chain length of C_{12} and above has been shown to be minimal. Aliphatic alcohols have no skin sensitization potential. Repeated exposure to aliphatic alcohols is generally without significant systemic toxicological findings and regarded to be of a low order of toxicity upon repeated exposure. C_6-C_{12} can induce local irritation at the site of first contact. There is a suggestion of mild change consistent with low-grade liver effects. Typical findings include: slightly increased liver weight, in some cases accompanied by clinical chemical changes but generally without concurrent histopathological effects. Aliphatic alcohols do not have a potential for producing peroxisome proliferation. Central nervous system (CNS) effects were absent upon inhalation or dietary administration, however 1-hexanol and 1-octanol showed a potential for CNS depression upon repeated administration of a bolus dose. Similarly, 1-hexanol and 1-octanol induced respiratory distress upon repeated administration of a bolus dose. Aliphatic alcohols do not have a potential for peripheral neuropathy. Typical no observable adverse effects level (NOAEL) for aliphatic alcohols range from 200 mg/kg/day to 1000 mg/kg/day in the rat upon sub-chronic administration via the diet. There has not been evidence of a carcinogenic potential for aliphatic alcohols. They do not contain structural elements of concern for potential interaction with DNA and have been shown to be without mutagenic activity, primarily on the basis of Ames assays and mouse micronucleus assays (Nelson et al., 1990a; OECD, 2006).

On the basis of the lack of adverse findings in the reproductive organs in repeated dose toxicity studies and in screening studies for reproductive effects aliphatic alcohols are considered without a potential for adverse effects on fertility and reproductive toxicity. Similarly, developmental toxicity studies with aliphatic alcohols have confirmed the lack of potential adverse effects on the developing fetus. As a rule aliphatic alcohols are manufactured and processed in established chemical complexes in closed installations; these are usually operated at high temperature and pressure. At these sites standard personal protective equipment is routinely applied to prevent direct skin and eye contact. Generally, aliphatic alcohols are of a low volatility and as a rule engineering controls are available preventing the need for respiratory protection. For non-routine operations involving a break in enclosed systems a higher level of protection is applied. Operations with a potential for significant exposure require a permit to work system and a case-by-case assessment is made for appropriate protective measures. Exposure through the use of products in industry and commerce is mitigated by applying measures aimed to prevent direct skin and eye contact by following the recommendations in the material safety data sheet (MSDS). Aliphatic alcohols are formulated in consumer laundry, cleaning and personal care products. Product labels reflect the hazard potential of the chemical ingredients in these products and include first aid instructions in case of non-intentional exposure (Nelson et al., 1990b; OECD, 2006).

Evaluation Question #11: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

Tobacco is apically dominant. The growing point via plant hormones exerts an influence throughout the vegetative and most of the reproductive phases, preventing the development of the axillary buds. Topping causes the axillary buds of the upper leaves to develop rapidly into suckers that must be removed at regular intervals until the final harvest. The suckers provide a harbor for insects and plant diseases. The use of a chemical for suckering and/or for topping results in a saving of labor, reduced infestations of insect pests, reduced spread of plant diseases, for example mosaic. There would also be less damage to the crop as a result of less travel through it. Indoleacetic acid at 10,000 ppm applied in lanolin will prevent sucker growth. Mineral oil daubed on the stem after topping also prevents sucker growth (Calvert, 1953).

Ten percent neem oil, 20% mohua oil, 25% groundnut oil and mineral oil applied to each plant after topping were evaluated against hand topping and suckering. All of these treatments improved sucker control and yield (Bangaryya et al., 1982).

Methyl caprate has been used effectively for topping and suckering. Although this fatty acid is an oleochemical, it may also be possible to produce it by fermentation (Tso, 1964).

Mineral oil, properly used can produce results in chemical suckering that are similar to hand suckering. However, some mineral oils may be too dangerous to use or must be diluted (emulsified) otherwise the oil may not only remove the suckers, but also burn the leaves. Mineral oil treatment is affected by rain. The use of mineral oil saves labor costs and exposure of personnel to nicotine and potentially green tobacco syndrome. Labor savings can be significant and as much 50% (Salmon, 1959; Wilson et al., 1952).

Apical dominance in tobacco can be controlled with plant growth hormones. However the removal of the tobacco inflorescence, topping acts as an immediate stimulus for the growth of suckers. The use of mineral and vegetable oil for suckering has the potential to cause or exacerbate soft rot. The cause may be too much oil and it running down the plant to contact roots. Highly refined mineral oil with very low aromatic content should be used. Liquid paraffin, white oil and light medicinal oil have been successfully used for suckering. Although it takes about twice as long to apply the oil as it does to hand sucker, subsequent manual suckering sessions are eliminate saving time and labor (Calvert, 1956b).

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Evaluation Question #12: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

When the tobacco crop is about half-grown, flower buds begin to appear. These flower heads are removed or "topped" to prevent seed formation, forcing the plant to focus on leaf production. The result is larger, thicker, darker leaves that mature more uniformly and contain more nicotine. Topping may be done by hand or with special machines that cut the flower heads and sacrifice a few leaves. Topping requires two or three trips over the field to catch all the plants. Topping of plants also stimulates the growth of secondary stems from the base and/or leaf axils. These "suckers" must also be removed to assure uniformity and quality. While chemicals are available to suppress suckering, these may not be allowable under organic certification standards. The alternative is removal by hand every seven to ten days. Suckering is one of the most labor-intensive activities in tobacco production, as many plants sucker two or three times before harvest (Kuepper and Thomas, 2008).

The aim of sucker control is to focus the plant's energy into filling the leaves rather than growing the flower. Because tobacco sells by weight, heavier leaves are favored economically. In organic tobacco production, early topping to improve yield and quality is usually done by hand. Suckers can be removed by hand as well as stunted by carefully applying approved soybean oil or mineral oil to the top of the plant. Topping and suckering are the most time consuming tasks associated with growing organic tobacco, and may be necessary every week for 10 weeks. It can take one person per acre per day to do the job. Plants may not be permitted to flower, instead, they are topped at 15 leaves. In organic tobacco production, controlling insects without insecticides and weeds without herbicides is not as big a big problem as controlling suckers. Application of mineral or cooking oil to prevent the suckers from coming back has to be done mostly by hand. Initial topping and suckering is done by hand. Vegetable oil or mineral oil is poured from gallon jugs over each plant, allowing the oil to run into each leaf axil to the way to the bottom of the plant. Topping early keeps the aphid off tobacco plants. Soybean cooking oil and mineral oil applied to the heads of plants prevents flowering. Eighteen hours can be spent per acre removing suckers (Little et al., 2008). There are currently 314 certified organic tobacco production operations. All of them are located in the United States of America (Organic Integrity Database).

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ITEM B.8 Regulatory Authority

Below is Information regarding EPA, FDA and State regulatory Authority registrations, including registration numbers:

EPA & State Registration Numbers:

End Use Product	EPA Reg. No.	States Registered
O-TAC PLANT CONTACT AGENT	51873-18	NC, OH, SC, TN, VA, GA, KY, CA
N-TAC (As a Plant contact Agent)	51873-20	NC

Active Substance	EPA Reg. No.
Active Ingredient C_6, C_8, C_{10}, C_{12} – Fatty Alcohol	63896-1

FDA Information:

Documentation that the Active Substance (fatty alcohol) ingredients used in the formulated products, N-TAC and O-TAC PLANT CONTACT AGENT, is approved as food additives by the U.S. Food and Drug Administration and are generally recognized as safe and meet the EPA Green Chemistry Requirement.

References (fatty alcohol):
Code of Federal Registrations, Title 21, Volume 3; Revised as of April 1, 2017; 21CFR172. 864, 5pp.

FDA

FDA Home[3] Medical Devices[4] Databases[5]

CFR - Code of Federal Regulations Title 21

The information on this page is current as of April 1 2017.

For the most up-to-date version of CFR Title 21, go to the Electronic Code of Federal Regulations (eCFR).[6]

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[Code of Federal Regulations]
[Title 21, Volume 3]
[Revised as of April 1, 2017]
[CITE: 21CFR172.864]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION (CONTINUED)
PART 172 -- FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION
Subpart I--Multipurpose Additives

Sec. 172.864 Synthetic fatty alcohols.

Synthetic fatty alcohols may be safely used in food and in the synthesis of food components in accordance with the following prescribed conditions:

(a) The food additive consists of any one of the following fatty alcohols:

(1) Hexyl, octyl, decyl, lauryl, myristyl, cetyl, and stearyl; manufactured by fractional distillation of alcohols obtained by a sequence of oxidation and hydrolysis of organo-aluminums generated by the controlled reaction of low molecular weight trialkylaluminum with purified ethylene (minimum 99 percent by volume C2H4), and utilizing the hydrocarbon solvent as defined in paragraph (b) of this section, such that:

(i) Hexyl, octyl, decyl, lauryl, and myristyl alcohols contain not less than 99 percent of total alcohols and not less than 96 percent of straight chain alcohols. Any nonalcoholic impurities are primarily paraffins.

(ii) Cetyl and stearyl alcohols contain not less than 98 percent of total alcohols and not less than 94 percent of straight chain alcohols. Any nonalcoholic impurities are primarily paraffins.

(iii) The synthetic fatty alcohols contain no more than 0.1 weight percent of total diols as determined by a method available upon request from the Commissioner of Food and Drugs.

(2) Hexyl, octyl, and decyl; manufactured by fractional distillation of alcohols obtained by a sequence of oxidation, hydrolysis, and catalytic hydrogenation (catalyst consists of copper, chromium, and nickel) of organo-aluminums generated by the controlled reaction of low molecular weight trialkylaluminum with purified ethylene (minimum 99 percent by volume C2H4), and utilizing an external coolant such that these alcohols meet the specifications prescribed in paragraph (a)(1) (i) and (iii) of this section.

(3) n-Octyl; manufactured by the hydrodimerization of 1,3-butadiene, followed by catalytic hydrogenation of the resulting dienol, and distillation to produce *n* -octyl alcohol with a minimum purity of 99 percent. The analytical method for *n* -octyl alcohol entitled "Test Method [Normal-octanol]" dated October 2003, and printed by Kuraray Co.,

Ltd., is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the Office of Food Additive Safety, 5001 Campus Dr., College Park, MD 20740, or you may examine a copy at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(b) The hydrocarbon solvent used in the process described in paragraph (a)(1) of this section is a mixture of liquid hydrocarbons essentially paraffinic in nature, derived from petroleum and refined to meet the specifications described in paragraph (b)(1) of this section when subjected to the procedures described in paragraph (b) (2) and (3) of this section.

(1) The hydrocarbon solvent meets the following specifications:

(i) Boiling-point range: 175 deg. C-275 deg. C.

(ii) Ultraviolet absorbance limits as follows:

Wavelength (millicrons)	Maximum absorbance per centimeter optical path length
280-289	0.15
290-299	.12
300-359	.05
360-400	.02

(2) Use ASTM method D86-82, "Standard Method for Distillation of Petroleum Products," which is incorporated by reference, to determine boiling point range. Copies of the material incorporated by reference may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(3) The analytical method for determining ultraviolet absorbance limits is as follows:

General Instructions

All glassware should be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure, it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of hydrocarbon solvent samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

Apparatus

Chromatographic tube. 450 millimeters in length (packing section), inside diameter 19 millimeters +/-1 millimeter, equipped with a wad of clean Pyrex brand filtering wool (Corning Glass Works Catalog No. 3950 or equivalent). The tube shall contain a 250-milliliter reservoir and a 2-millimeter tetrafluoroethylene polymer stopcock at the opposite end. Overall length of the tube is 670 millimeters.

Stainless steel rod. 2 feet in length, 2 to 4 millimeters in diameter.

Vacuum oven. Similar to Labline No. 3610 but modified as follows: A copper tube one-fourth inch in diameter and 13 inches in length is bent to a right angle at the 4-inch point and plugged at the opposite end; eight copper tubes one-eighth inch in diameter and 5 inches in length are silver soldered in drilled holes (one-eighth inch in diameter) to the one-fourth-inch tube, one on each side at the 5-, 7.5-, 10- and 12.5-inch points; the one-eighth-inch copper tubes are bent to conform with the inner periphery of the oven.

Beakers. 250-milliliter and 500-milliliter capacity.

Graduated cylinders. 25-milliliter, 50-milliliter, and 150-milliliter capacity.

Tuberculin syringe. 1-milliliter capacity, with 3-inch, 22-gauge needle.

Volumetric flask. 5-milliliter capacity.

Spectrophotometric cells. Fused quartz ground glass stoppered cells, optical path length in the range of 1.000 centimeter +/-0.005 centimeter. With distilled water in the cells, determine any absorbance difference.

Spectrophotometer. Spectral range 250 millimicrons--400 millimicrons with spectral slit width of 2 millimicrons or less: under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, +/-0.01 at 0.4 absorbance.

Absorbance accuracy, [1] +/-0.05 at 0.4 absorbance.

Wavelength repeatability, +/-0.2 millimicron.

Wavelength accuracy, +/-1.0 millimicron.

Nitrogen cylinder. Water-pumped or equivalent purity nitrogen in cylinder equipped with regulator and valve to control flow at 5 p.s.i.g.

Reagents and Materials

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The isooctane, benzene, hexane, and 1,2-dichloroethane designated in the list following this paragraph shall pass the following test:

To the specified quantity of solvent in a 250-milliliter beaker, add 1 milliliter of purified *n*- hexadecane and evaporate in the vacuum oven under a stream of nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. (To the residue from benzene add a 5-milliliter portion of purified isooctane, reevaporate, and repeat once to insure complete removal of benzene.)

Dissolve the 1 milliliter of hexadecane residue in isooctane and make to 5 milliliters volume. Determine the absorbance in the 1-centimeter path length cells compared to isooctane as reference. The absorbance of the solution of the solvent residue shall not exceed 0.02 per centimeter path length between 280 and 300 m[micro] and shall not exceed 0.01 per centimeter path length between 300 and 400 m[micro].

Isooctane (2,2,4-trimethylpentane). Use 10 milliliters for the test described in the preceding paragraph. If necessary, isooctane may be purified by passage through a column of activated silica gel (Grade 12, Davison Chemical Co., Baltimore, Md., or equivalent).

Benzene, spectro grade (Burdick and Jackson Laboratories, Inc., Muskegon, Mich., or equivalent). Use 80 milliliters for the test. If necessary, benzene may be purified by distillation or otherwise.

Hexane, spectro grade (Burdick and Jackson Laboratories, Inc., Muskegon, Mich., or equivalent). Use 650 milliliters for the test. If necessary, hexane may be purified by distillation or otherwise.

1,2-Dichloroethane, spectro grade (Matheson, Coleman, and Bell, East Rutherford, N.J., or equivalent). Use 20 milliliters for test. If necessary, 1,2-dichloroethane may be purified by distillation.

Eluting mixtures:

1. *10 percent 1,2-dichloroethane in hexane.* Pipet 100 milliliters of 1,2-dichloroethane into a 1-liter glass-stoppered volumetric flask and adjust to volume with hexane, with mixing.

2. *40 percent benzene in hexane.* Pipet 400 milliliters of benzene into a 1-liter glass-stoppered volumetric flask and adjust to volume with hexane, with mixing.

n-Hexadecane, 99 percent olefin-free. Dilute 1.0 milliliter of *n*- hexadecane to 5 milliliters with isooctane and determine the absorbance in a 1-centimeter cell compared to isooctane as reference between 280 m[micro]-400m[micro]. The absorbance per centimeter path length shall not exceed 0.00 in this range. If necessary, *n*- hexadecane may be purified by percolation through activated silica gel or by distillation.

Silica gel, 28-200 mesh (Grade 12, Davison Chemical Co., Baltimore, Md., or equivalent). Activate as follows: Weigh about 900 grams into a 1-gallon bottle, add 100 milliliters of de-ionized water, seal the bottle and shake and roll at intervals for 1 hour. Allow to equilibrate overnight in the sealed bottle. Activate the gel at 150 deg. C for 16 hours, in a 2-inch * 7-inch * 12-inch porcelain pan loosely covered with aluminum foil, cool in a dessicator, transfer to a bottle and seal.

Procedure

Determination of ultraviolet absorbance. Before proceeding with the analysis of a sample determine the absorbance in a 1-centimeter path cell for the reagent blank by carrying out the procedure without a sample. Record the absorbance in the wavelength range of 280 to 400 millimicrons. Typical reagent blank absorbance in this range should not exceed 0.04 in the 280 to 299 millimicron range, 0.02 in the 300 to 359 millimicron range, and 0.01 in the 360 to 400 millimicron range. If the characteristic benzene peaks in the 250 to 260 millimicron region are present, remove the benzene by the procedure described above under "Reagents and Materials," "Organic Solvents," and record absorbance again.

Transfer 50 grams of silica gel to the chromatographic tube for sample analysis. Raise and drop the column on a semisoft, clean surface for about 1 minute to settle the gel. Pour 100 milliliters of hexane into the column with the stopcock open and allow to drain to about one-half inch above the gel. Turn off the stopcock and allow the column to cool for 30 minutes. After cooling, vibrate the column to eliminate air and stir the top 1 to 2 inches with a small diameter stainless steel rod. Take care not to get the gel above the liquid and onto the sides of the column.

Weigh out 40 grams +/-0.1 gram of the hydrocarbon solvent sample into a 250-milliliter beaker, add 50 milliliters of hexane, and pour the solution into the column. Rinse the beaker with 50 milliliters of hexane and add this to the column. Allow the hexane sample solution to elute into a 500-milliliter beaker until the solution is about one-half inch above the gel. Rinse the column three times with 50-milliliter portions of hexane. Allow each hexane rinse to separately elute to about one-half inch above the gel. Replace the eluate beaker (discard the hexane eluate) with a 250-milliliter beaker. Add two separate 25-milliliter portions of 10 percent 1,2-dichloroethane and allow each to separately elute as before. Finally, add 150 milliliters of 10 percent 1,2-dichloroethane for a total of 200 milliliters. When the final 10 percent 1,2-dichloroethane fraction is about one-half inch above the top of the gel bed, replace the receiving beaker (discard the 1,2-dichloroethane eluate) with a 250-milliliter beaker containing 1 milliliter of hexadecane. Adjust the elution rate to 2 to 3 milliliters per minute, add two 25-milliliter portions of 40 percent benzene and allow each to separately elute as before to within about one-half inch of the gel bed. Finally, add 150 milliliters of 40 percent benzene for a total of 200 milliliters. Evaporate the benzene in the oven with vacuum and sufficient nitrogen flow to just ripple the top of the benzene solution. When the benzene is removed (as determined by a constant volume of hexadecane) add 5 milliliters of isooctane and evaporate. Repeat once to insure complete removal of benzene. Remove the beaker and cover with aluminum foil (previously rinsed with hexane) until cool.

Quantitatively transfer the hexadecane residue to a 5-milliliter volumetric flask and dilute to volume with isooctane. Determine the absorbance of the solution in 1-centimeter path length cells between 280 and 400 millimicrons using isooctane as a reference. Correct the absorbance values for any absorbance derived from reagents as determined by carrying out the procedure without a sample. If the corrected absorbance does not exceed the limits prescribed in paragraph (b)(1)(ii) of this section, the sample meets the ultraviolet absorbance specifications for hydrocarbon solvent.

(c) Synthetic fatty alcohols may be used as follows:

(1) As substitutes for the corresponding naturally derived fatty alcohols permitted in food by existing regulations in this part or part 173 of this chapter provided that the use is in compliance with any prescribed limitations.

(2) As substitutes for the corresponding naturally derived fatty alcohols used as intermediates in the synthesis of food additives and other substances permitted in food.

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[1] As determined by using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce, (1949). The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons. Circular 484 is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information

on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 11837, Mar. 19, 1982; 49 FR 10105, Mar. 19, 1984; 54 FR 24897, June 12, 1989; 70 FR 72908, Dec. 8, 2005; 81 FR 5591, Feb. 3, 2016]

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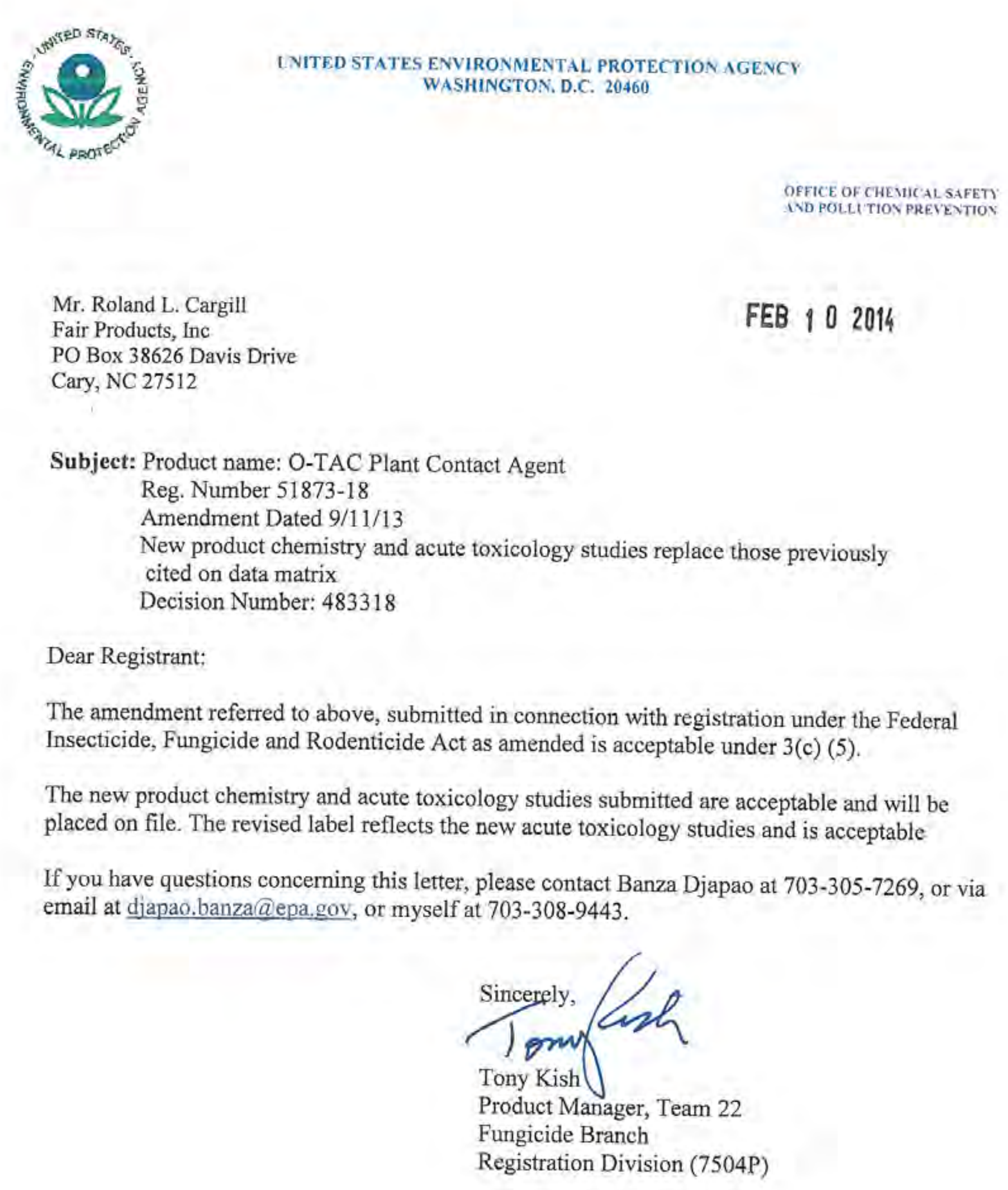
ITEM B.9 Chemical Abstracts Service (CAS) Number and Product Labels

CAS Number:
Active Ingredients C_6, C_8, C_{10}, C_{12} - **Naturally Derived Fatty Alcohol;**
68603-15-6 –trade name **Mascol 80**

Below are copies of EPA letters with labels approving O-TAC PLANT CONTACT AGENT and N-TAC, as well as a copy of the North Carolina Department of Agriculture- Pesticide Registration Certification and O-TAC Product Review and Material Verification.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

FEB 10 2014

Mr. Roland L. Cargill
Fair Products, Inc
PO Box 38626 Davis Drive
Cary, NC 27512

Subject: Product name: O-TAC Plant Contact Agent
Reg. Number 51873-18
Amendment Dated 9/11/13
New product chemistry and acute toxicology studies replace those previously cited on data matrix
Decision Number: 483318

Dear Registrant:

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act as amended is acceptable under 3(c) (5).

The new product chemistry and acute toxicology studies submitted are acceptable and will be placed on file. The revised label reflects the new acute toxicology studies and is acceptable

If you have questions concerning this letter, please contact Banza Djapao at 703-305-7269, or via email at djapao.banza@epa.gov, or myself at 703-308-9443.

Sincerely,

Tony Kish

Tony Kish
Product Manager, Team 22
Fungicide Branch
Registration Division (7504P)

** Proposed changes in Red**

O-TAC PLANT CONTACT AGENT®

CONTACT TOBACCO SUCKER CONTROL AGENT

KEEP OUT OF REACH OF CHILDREN

DANGER - PELIGRO

PRECAUCION AL USUARIO: Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail)

READ ENTIRE LABEL CAREFULLY BEFORE USING THIS PRODUCT.

ACTIVE INGREDIENTS: (% by weight)

Octanol (C_8)	36.2%
Decanol (C_{10})	48.2%
Related Compounds (dodecanol C_{12})	0.3%
OTHER INGREDIENTS:	15.3%
TOTAL	100%

This product contains 2.57 lb. octanol 3.43 lb. decanol and 0.02 lb. dodecanol per gallon. If not used in accordance with directions, plant injury, excessive residues, or other undesirable results may occur.

Sold by:
Fair Products, Inc., USA
Agri-Specialties Division
Post Office Box 386
Cary, North Carolina 27512
Telephone: (919) 467-8352

MADE IN U.S.A.
EPA REG. NO. 51873-18
EPA EST. NO. 45671-NC-01
10192012V-2013P

NET CONTENTS:
18.93 LITERS
5 GALLONS

ACCEPTED
FEB 10 2014
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under
EPA Reg. No. 51873-18

O-TAC PLANT CONTACT AGENT/Left side panel, p. 1

FIRST AID

If In Eyes	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye • Call a poison control center or doctor for treatment advice.
If On Skin or Clothing	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If Swallowed	• Call a poison control center or doctor for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person
If Inhaled	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Have the container or label with you when calling a poison control center or doctor or going for treatment. **For emergency information pertaining to the product and contact with eyes call (919)-467-8352, Monday through Friday 9AM to 5PM EST. After 5PM call your Poison Control Center or Call the National Poison Control Hotline at 1-800-222-1222 for additional information.**

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER

Corrosive. Causes irreversible eye damage. Wear protective eyewear (goggles, face shield, or safety glasses). Harmful if absorbed through skin. Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using toilet. Remove and wash contaminated clothing before reuse. Avoid contact with skin, eyes or clothing. Wear long-sleeved shirt and long pants, socks, shoes, and gloves (such as or made out of any waterproof material, selection category A).

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are made of barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, or viton. If you want more options, follow the instructions for **CATEGORY C** on an EPA chemical resistance category selection chart.

MIXERS, LOADERS, APPLICATORS AND OTHER HANDLERS MUST WEAR:

- Goggles or faceshield
- Coveralls over short-sleeved shirt and short pants
- Chemical resistant footwear plus socks, and
- Chemical resistant gloves

USER SAFETY REQUIREMENTS

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables **exist**, use detergent and hot water. Keep and wash PPE separately from other laundry.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the Restricted Entry Interval (REI) of 24 hours.

PPE required for early entry into treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical resistant gloves
- Shoes plus socks
- Protective eyewear

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning equipment or disposal of waste.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

1. **PESTICIDE STORAGE -** Do not stack over 2 pallets high. Store original containers in cool dry place away from food, water and feed.

2. **PESTICIDE DISPOSAL** - Pesticide wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

3. **CONTAINER DISPOSAL** – Non-refillable containers. Do not reuse or refill this container. **For container sizes of 5 gallons or less,** triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and draining for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

For container sizes greater than 5 gallons, triple rinse as follows: empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least on complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinate for later use or disposal. Repeat the procedure two more times. Then offer for recycling if available, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or persons, either directly or indirectly through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

O-TAC PLANT CONTACT AGENT is a carefully balanced combination of active ingredients and wetting agents to be used for the control of sucker growth on Burley, Flue-Cured, Dark Fired, Maryland and Cigar tobacco. The concentrated product is diluted with water to form a creamy emulsion, which is applied as a coarse spray. The emulsion is effective only when it comes in direct contact with suckers; therefore, the material is applied so that maximum contact is made with the suckers.

WHEN TO APPLY:

O-TAC PLANT CONTACT AGENT can be applied before or after topping. Best results are usually obtained by spraying the tobacco with O-TAC PLANT CONTACT AGENT before topping in the early to late button stage and then topping the tobacco immediately followed by additional applications of O-TAC PLANT CONTACT AGENT starting and spaced 3 to 5 days apart. If you top the tobacco before spraying, remove any suckers over one inch in length as you top and apply O-TAC PLANT CONTACT AGENT after topping. Because O-TAC PLANT CONTACT AGENT is a contact type agent, it is necessary to straighten any plants that are leaning so that the emulsion flows down the stalk evenly and contacts each sucker.

O-TAC PLANT CONTACT AGENT usually can be applied anytime during the day, but not to wilted plants. For best results, it is recommended that you wait until the dew dries before spraying. Do not spray after the leaves begin to close in the evening. Because the underside of the leaves may be injured by contact with O-TAC PLANT CONTACT AGENT, do not apply when the wind is high enough to turn the top leaves over. Do not apply during the rain or when plants are wet. If however, it rains after O-TAC PLANT CONTACT AGENT has been on the plants for over an hour, you should not have to apply O-TAC PLANT CONTACT AGENT again. Do not apply during periods of high heat or if plants are wilted.

HOW MUCH O-TAC PLANT CONTACT AGENT TO APPLY:

For each tobacco type listed use the lower rate and apply to untopped plants in the button stage when plant tissue is tender, then top immediately. Use the higher rate for the first application when plants are more mature and for the second application 3 to 5 days later followed by additional applications 3 to 5 days apart as needed.

Flue-Cured: For power sprayer - use 2 gallons (7.57 liters) in 48 gallons (182 liters) of water, for a total spray solution of 50 gallons (189 liters) –4% solution; or 2.5 gallons (9.4 liters) in 47.5 gallons (180 liters) of water for a total spray solution of 50 gallons (189 liters) – 5% solution.

For hand sprayer - use 5 ounces (148 milliliters) in water to make a total of 1 gallon (3.785 liters) of spray (4% solution), or 6 ounces (177 milliliters) in water to make a total of 1 gallon (3.785 liters) of spray (5% solution).

NOTE: In the event of an extended season, later applications of 2.5 gallons (9.4 liters) O-TAC PLANT CONTACT AGENT in 47.5 gallons (180 liters) water (5% concentration) may be made.

Burley: For power sprayer - use 1.75 to 2 gallons (6.62-7.57 liters) in water to make a total of 50 gallons (189 liters) of spray solution (3.5 to 4% solution).

Dark Fired: For hand sprayer, use 6 to 8 ounces (177-237 milliliters) in water to make a total of 1 gallon (3.785 liters) of spray (4.5 - 6% solution).

Cigar: Use 4 to 5 ounces (118-148 milliliters) in water to make a total of 1 gallon (3.785 liters) of spray solution to apply with a hand sprayer (3 – 4 % solution).

Maryland: Use 4 to 4.5 ounces (118-133 milliliters) in water to make a total of 1 gallon (3.785 liters) of spray solution to apply with a hand sprayer (3 to 3.5% solution).

When applied by hand using 2/3 to 1 ounce (20 - 30 milliliters) of spray solution per plant, 1 gallon (3.785 liters) of diluted O-TAC PLANT CONTACT AGENT will treat 128-190 plants.

If a power sprayer is used, 50 gallons (189 liters) of diluted product should be applied per acre of tobacco.

HOW TO APPLY:
The diluted emulsion is most easily prepared by adding the required amount of O-TAC PLANT CONTACT AGENT to your spray tank and then adding the water. In order to obtain the best results, it is important that the water be added to the O-TAC PLANT CONTACT AGENT rather than the O-TAC PLANT CONTACT AGENT to the water to enhance mixing and reduce floating.

If you use a hand-held or backpack sprayer, the diluted solution must be applied at a rate of 2/3 to 1 ounce (20-30 milliliters) per plant (or enough to insure rundown to the bottom of the plant). A coarse spray is recommended, directed downward at the top of the stalk from 6-8 inches above the top leaves, very little tank pressure is required, and in no case should more than 20 pounds be used.

When applied with power equipment, three nozzles per row must be used (TG full cone tips, or larger, are satisfactory). One TG-5 nozzle should be directed downward over the center of the row and two TG-3s should be positioned approximately 11 inches on either side directed at or slightly above the top of the stalk. The diluted O-TAC PLANT CONTACT AGENT must be applied to the tobacco as a coarse spray from a height of 12 to 16 inches above the top of the stalk. It is recommended that boom pressure be kept at 20 lbs. By using the recommended spray tips, spraying at approximately 20 lbs. pressure, and operating a tractor speed of 2.5 to 3 mph, you will apply approximately 50 gallons of diluted solution per acre of tobacco.

HOW OFTEN TO APPLY:
Usually one application of O-TAC PLANT CONTACT AGENT will give good control of both primary and secondary suckers and produce excellent leaf quality. However, in most cases additional treatments of O-TAC PLANT CONTACT AGENT are recommended 3 to 5 days apart to allow time for uneven crops to become uniform.

NOTES:

1. Mix well prior to use and, if allowed to stand during the use, mix again before applying since the diluted emulsion may separate on standing.
2. Do not use on Burley tobacco during periods of high heat and high humidity.
3. Usage according to the directions outlined has resulted in adequate sucker control with very little or no leaf injury. Application not in accordance with the directions may lead to injury of leaves or improper sucker control.
4. Make sure spray equipment is clean before using.
5. Do not mix with other pesticides, fertilizers, surfactants or any other materials as plant damage or death may result.

WARRANTY STATEMENT: To the extent permitted by applicable law, Seller's guarantee shall be limited to the terms of the label, and subject thereto the buyer assumes any risk to persons or property arising out of use or handling and accepts the product on these conditions.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

FEB 10 2014

Mr. Roland L. Cargill
Fair Products, Inc
PO Box 38626 Davis Drive
Cary, NC 27512

Subject: Product name: N-TAC
Reg. Number 51873-20
Amendment Dated 9/11/13
New product chemistry and acute toxicology studies replace those previously cited on data matrix
Decision Number: 483319

Dear Registrant:

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act as amended is acceptable under 3(c) (5).

The new product chemistry and acute toxicology studies submitted are acceptable and will be placed on file. The revised label reflects the new acute toxicology studies and is acceptable

If you have questions concerning this letter, please contact Banza Djapao at 703-305-7269, or via email at djapao.banza@epa.gov, or myself at 703-308-9443.

Sincerely,

Tony Kish

Tony Kish
Product Manager, Team 22
Fungicide Branch
Registration Division (7504P)

** Proposed changes in Red**

ACCEPTED
FEB 10 2014
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 51873-20

N-TAC®

Tobacco Sucker Control

KEEP OUT OF REACH OF CHILDREN

DANGER - PELIGRO

PRECAUCION AL USUARIO: Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail)

READ ENTIRE LABEL CAREFULLY BEFORE USING THIS PRODUCT.

ACTIVE INGREDIENTS: (% by weight)	
Octanol (C_8)	36.2%
Decanol (C_{10})	48.2%
Related Compounds (dodecanol C_{12})	0.3%
OTHER INGREDIENTS:	15.3%
TOTAL	100%

This product contains 2.57 lb. octanol 3.41 lb. decanol and 0.02 lb. dodecanol per gallon. If not used in accordance with directions, plant injury, excessive residues, or other undesirable results may occur.

Sold by:
Fair Products, Inc., USA
Agri-Specialties Division
Post Office Box 386
Cary, North Carolina 27512
Telephone: (919) 467-8352

MADE IN U.S.A.
EPA REG. NO. 51873-20
EPA EST. NO. 45671-NC-01
07182013V-2013P

NET CONTENTS:
5 GALLONS
18.93 LITERS

FIRST AID

If In Eyes	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye • Call a poison control center or doctor for treatment advice.
If On Skin or Clothing	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If Swallowed	• Call a poison control center or doctor for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything to an unconscious person
If Inhaled	• Move person to fresh air • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Have the container or label with you when calling a poison control center or doctor or going for treatment. **For emergency information pertaining to the product and contact with eyes call (919)-467-8352, Monday through Friday 9AM to 5PM EST. After 5PM call your Poison Control Center or Call the National Poison Control Hotline at 1-800-222-1222 for additional information.**

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER

Corrosive. Causes irreversible eye damage. Wear protective eyewear (goggles, face shield, or safety glasses). Harmful if absorbed through skin. Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using toilet. Remove and wash contaminated clothing before reuse. Avoid contact with skin, eyes or clothing. Wear long-sleeved shirt and long pants, socks, shoes, and gloves (such as or made out of any waterproof material, selection category A).

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are made of barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, or viton. If you want more options, follow the instructions for **CATEGORY C** on an EPA chemical resistance category selection chart.

MIXERS, LOADERS, APPLICATORS AND OTHER HANDLERS MUST WEAR:

- Goggles or faceshield
- Coveralls over short-sleeved shirt and short pants
- Chemical resistant footwear plus socks, and
- Chemical resistant gloves

USER SAFETY REQUIREMENTS

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the Restricted Entry Interval (REI) of 24 hours.

PPE required for early entry into treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical resistant gloves
- Shoes plus socks
- Protective eyewear

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning equipment or disposal of waste.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

1. **PESTICIDE STORAGE** - Do not stack over 2 pallets high. Store original containers in cool dry place away from food, water and feed.

2. **PESTICIDE DISPOSAL** - Pesticide wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

3. **CONTAINER DISPOSAL** – Non-refillable containers. Do not reuse or refill this container. **For container sizes of 5 gallons or less**, triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and draining for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

   For container sizes greater than 5 gallons, triple rinse as follows: empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least on complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinate for later use or disposal. Repeat the procedure two more times. Then offer for recycling if available, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

DIRECTIONS FOR USE

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N-TAC is a carefully balanced combination of active ingredients and wetting agents to be used for the control of sucker growth on Burley, Flue-Cured, Dark Fired, Maryland and Cigar tobacco. The concentrated product is diluted with water to form a creamy emulsion, which is applied as a coarse spray. The emulsion is effective only when it comes in direct contact with suckers; therefore, the material is applied so that maximum contact is made with the suckers.

WHEN TO APPLY:
N-TAC can be applied before or after topping. Best results are usually obtained by spraying the tobacco with N-TAC before topping in the early to late button stage and then topping the tobacco immediately followed by additional applications of N-TAC starting and spaced 3 to 5 days apart. If you top the tobacco before spraying, remove any suckers over one inch in length as you top and apply N-TAC after topping. Because N-TAC is a contact type agent, it is necessary to straighten any plants that are leaning so that the emulsion flows down the stalk evenly and contacts each sucker.

N-TAC usually can be applied anytime during the day, but not to wilted plants. For best results, it is recommended that you wait until the dew dries before spraying. Do not spray after the leaves begin to close in the evening. Because the underside of the leaves may be injured by contact with N-TAC, do not apply when the wind is high enough to turn the top leaves over. Do not apply during the rain or when plants are wet. If however, it rains after N-TAC has been on the plants for over an hour, you should not have to apply N-TAC again. Do not apply during periods of high heat or if plants are wilted.

HOW MUCH N-TAC TO APPLY:
For each tobacco type listed use the lower rate and apply to untopped plants in the button stage when plant tissue is tender, then top immediately.
Use the higher rate for the first application when plants are more mature and for the second application 3 to 5 days later followed by additional applications 3 to 5 days apart as needed.

Flue-Cured:	For power sprayer - use 2 gallons (7.57 liters) in 48 gallons (182 liters) of water, for a total spray solution of 50 gallons (189 liters) –4% solution; or 2.5 gallons (9.4 liters) in 47.5 gallons (180 liters) of water for a total spray solution of 50 gallons (189 liters) – 5% solution. For hand sprayer - use 5 ounces (148 milliliters) in water to make a total of 1 gallon (3.785 liters) of spray (4% solution), or 6 ounces (177 milliliters) in water to make a total of 1 gallon (3.785 liters) of spray (5% solution). **NOTE:** In the event of an extended season, later applications of 2.5 gallons (9.4 liters) N-TAC in 47.5 gallons (180 liters) water (5% concentration) may be made.
Burley:	For power sprayer - use 1.75 to 2 gallons (6.62-7.57 liters) in water to make a total of 50 gallons (189 liters) of spray solution (3.5 to 4% solution).
Dark Fired:	For hand sprayer, use 6 to 8 ounces (177-237 milliliters) in water to make a total of 1 gallon (3.785 liters) of spray (4.5 - 6% solution).
Cigar:	Use 4 to 5 ounces (118-148 milliliters) in water to make a total of 1 gallon (3.785 liters) of spray solution to apply with a hand sprayer (3 – 4 % solution).
Maryland:	Use 4 to 4.5 ounces (118-133 milliliters) in water to make a total of 1 gallon (3.785 liters) of spray solution to apply with a hand sprayer (3 to 3.5% solution).

When applied by hand using 2/3 to 1 ounce (20 - 30 milliliters) of spray solution per plant, 1 gallon (3.785 liters) of diluted N-TAC will treat 128-190 plants.

If a power sprayer is used, 50 gallons (189 liters) of diluted product should be applied per acre of tobacco.

HOW TO APPLY:
The diluted emulsion is most easily prepared by adding the required amount of N-TAC to your spray tank and then adding the water. In order to obtain the best results, it is important that the water be added to the N-TAC rather than the N-TAC to the water to enhance mixing and reduce floating.

If you use a hand-held or backpack sprayer, the diluted solution must be applied at a rate of 2/3 to 1 ounce (20-30 milliliters) per plant (or enough to insure rundown to the bottom of the plant). A coarse spray is recommended, directed downward at the top of the stalk from 6-8 inches above the top leaves, very little tank pressure is required, and in no case should more than 20 pounds be used.

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HOW OFTEN TO APPLY:
Usually one application of N-TAC will give good control of both primary and secondary suckers and produce excellent leaf quality. However, in most cases additional treatments of N-TAC are recommended 3 to 5 days apart to allow time for uneven crops to become uniform.

NOTES:

1. Mix well prior to use and, if allowed to stand during the use, mix again before applying since the diluted emulsion may separate on standing.
2. Do not use on Burley tobacco during periods of high heat and high humidity.
3. Usage according to the directions outlined has resulted in adequate sucker control with very little or no leaf injury. Application not in accordance with the directions may lead to injury of leaves or improper sucker control.
4. Make sure spray equipment is clean before using.
5. Do not mix with other pesticides, fertilizers, surfactants or any other materials as plant damage or death may result.

WARRANTY STATEMENT: To the extent permitted by applicable law, Seller's guarantee shall be limited to the terms of the label, and subject thereto the buyer assumes any risk to persons or property arising out of use or handling and accepts the product on these conditions.

****
*FOR YOUR RECORDS *
NOT TO BE RETURNED
THIS IS NOT A BILL
****

NORTH CAROLINA DEPARTMENT OF AGRICULTURE
PESTICIDE SECTION
STEVE TROXLER, COMMISSIONER

PESTICIDE REGISTRATION CERTIFICATION

THIS CERTIFIES THAT THE BRANDS OR GRADES OF PESTICIDE(S) LISTED BELOW HAVE BEEN DULY REGISTERED, AND THEIR SALES IN NORTH CAROLINA AUTHORIZED FOR THE CALENDAR YEAR INDICATED, ACCORDING TO THE NORTH CAROLINA PESTICIDE LAW OF 1971, ARTICLE 52 OF CHAPTER 143 OF THE GENERAL STATUTES.

SUBMITTED FOR: 000001231
FAIR PRODUCTS INC
RENEE ALLEN
PO BOX 386
CARY NC 27515

SUBMITTED BY: 000001231
FAIR PRODUCTS INC
RENEE ALLEN
PO BOX 386
CARY NC 27515

PHONE: (919)467-1599

EPA REG NO		BRAND NAME OF PESTICIDE (AS SHOWN ON LABEL)	NC ID	STATUS	REG FEE	ETF FEE	REG YEAR
051873-00002-	-	FAIR PLUS FOR THE PREVENTION OF GROWTH OF TOBACCO SUCKERS	19881729	RENEWAL	$150.00	$50.00	2018
051873-00005-	-	FAIR TAC CONTACT TOBACCO SUCKER CONTROL AGENT	20011991	RENEWAL	$150.00	$50.00	2018
051873-00006-	-	FST-7 CONTACT & SYSTEMIC TOBACCO SUCKER CONTROL AGENT	19881730	RENEWAL	$150.00	$50.00	2018
051873-00007-	-	FAIR 85 CONTACT TOBACCO SUCKER CONTROL AGENT	19881728	RENEWAL	$150.00	$50.00	2018
051873-00008-	-	DE-CUT TO CONTROL & RETARD PLANT GROWTH IN ACRES DIFFICULT TO MAINTAI	19881731	RENEWAL	$150.00	$25.00	2018
051873-00009-	-	FAIR 30 FOR THE PREVENTION OF GROWTH OF TOBACCO SUCKERS	19881732	RENEWAL	$150.00	$50.00	2018
051873-00017-	-	FAIR 80 SP FOR THE SYSTEMIC PREVENTION OF TOBACCO SUCKER GROWTH	19960990	RENEWAL	$150.00	$50.00	2018
051873-00018-	-	O-TAC PLANT CONTACT AGENT	20090689	RENEWAL	$150.00	$50.00	2018
051873-00020-	-	N-TAC TOBACCO SUCKER CONTROL	20131328	RENEWAL	$150.00	$50.00	2018

Chemical Abstracts Service (CAS) Number and Product Labels "Continued"

Independent Third Party Product Review and Material Verification for use in Organic Tobacco Crops Production: Below is a copy of this report for O-TAC PLANT CONTACT AGENT that was conducted on June 13, 2018.

Conclusion: "This operation was found to be in compliance with and adhering to the requirements necessary to comply with the organic regulations as set forth.

The Organic Food Act, Preamble to Final Rule and Section's, 205.400-406. Notwithstanding any other items that may be needed to complete that Review, the recommendation in approval for use in an organic tobacco crop production pursuant to 7CFR Section 205. 404."

INDEPENDENT THIRD PARTY PRODUCT REVIEW AND MATERIAL VERIFICATION
FOR USE IN CERTIFIED ORGANIC TOBACCO CROPS PRODUCTION

Attention: This report contains sensitive, confidential and proprietary information. Please handle this document in a confidential manner.

Date of Review: June13, 2018

PRODUCT/MATERIAL: O-TAC PLANT CONTACT AGENT (EPA #51873-18) – EPA Establishment #45671-NC-01, Contact Tobacco Sucker Control Agent

Independent Material/Product Verification Performed for:
Fair Products, Inc. – Agri Specialties Division
H. Frank Grainger
P.O. Box 386, Cary, North Carolina 27513
Phone 919-467-8352

Manufacturer: South Atlantic Services
P.O. Box 1886, Wilmington, North Carolina 28402

Product: O-TAC Plant Contact Agent EPA Establishment
Active Ingredients: Fatty Alcohols Blend, Octanol C8, (36.2%); Decanol C10 (48.2%); Related Compounds (Dodecanol C12 (0.3%). , the blend brings with it other alcohol derivatives.
Other Ingredients: 15.3% (OMRI approved) Inert Ingredients. (This is the surfactant used).

Purpose and Scope: This document will serve as a raw and finished product materials/verification of the above-named O-TAC product for use in Organic Tobacco Crop Systems at the request of the above entities, Fair Products, Inc. and South Atlantic Services.

BACKGROUND: The product was developed as an essential need product and/or valuable tool by both large and small family farms in order to produce a viable crop and implement strategies for sustainable growth methodologies. The product was first approved by an accredited certifying agent known as Quality Certification Services (QCS) for use on certified organic farms in 2009 for the purposes of providing an agent for use in controlling suckers on organic tobacco plants and has been in use since that year by organic farmers.

General information and current year requirements were verified in compliance with handling accreditation standards for products to be used under an organic systems plan. The reviewer noted no changes as submitted with regard to product information, certification history and previous production requirements. With regard to Permits, Registrations and Regulatory inspections the product meets and/or exceeds required governmental agency standards and all permits are approved and in place.

FINDINGS

Ingredient: There are two ingredients, Natural Fatty Alcohols made from Palm Kernel Oil and a Surfactant, supplied by Croda, Inc. The Surfactant is OMRI approved (Tween 80). P.T. Musim Mas is supplying the Natural Fatty Alcohol (MASCOL 80). This company has been the only supplier for this material since 2009. Information and Technical Documents for the suppliers and ingredients are provided in the file. These documents include Safety Data Sheets, Certificate of Analysis, Ionizing Radiation, Sewage Sludge and Genetically Modified Organism Disclosures as well as additional process/batch information. Croda Inc. is the supplier of the surfactant (Tween 80) being used and P. T. Musim Mas is supplying the Natural Fatty Alcohols (Mascol 80 Octyl Decyl Alcohol).

Storage/Blending:

Storage occurs upon arrival of raw material and follows the path for O-TAC Blending and Process Flow Chart. All received incoming Raw Materials are reviewed and sampled for laboratory testing. The Certificate of Analysis which accompanies each incoming purchase is compared to the laboratory testing criteria. This ensures that all materials received meet product specifications. Should the alcohol or surfactant materials fail to meet the requirements, then the product is rejected and unloading of the raw materials does not take place. Any materials not meeting the descriptions would not be used until the Supplier is contacted and a determination is made as to product status. To date, the manufacturer, South Atlantic Services notes all raw materials received have met or exceeded the specification standards agreed to by both entities for successful production.

The next step would be to unload the raw materials into the on site dedicated storage tanks. These tanks are for transfer, storage and blending of the O-TAC Product only. The reviewer notes that each tank is assigned a number to aid in production. There are 4 dedicated tanks in total. Two tanks hold 30,000 gallons each; one tank holds 26,000 gallons and the last tank holds 17,000 gallons. Tank #31 contains the Surfactant (Tween 80) supplied by Croda and Tank #32, contains a portion of the alcohol storage and is used for blending the O-TAC finished product. For the blending part of manufacture the amount of natural alcohol in the tank is determined and the proper amount of surfactant is added to the natural alcohol. The two ingredients are mixed by use of a dedicated process pump which circulates the liquid within the tank until properly mixed. Three of the tanks are used for storage and one of the tanks is kept for material storage and blending. All blended product is distributed through dedicated pipe lines to packing. (This is a dedicated production system.)

Organic Product Profile: 205.601 – 205.602.

The documentation and review verified that the product requested and the product profile as listed were complete and accurate. The product category for percentages of finished product, inputs, ingredient disclosure statements, and product formulations are complete and accurate. Raw materials, suppliers sourced, ingredients and product content, together with certificates, are verified to be current and accurate as documented. All formulations correspond to batch records sourced and labeling as noted in the files. The O-TAC Blending Process is proprietary information and as such will not be discussed by the reviewer. No other recommendations are made, except as noted in this report.

Labeling of Products: 7CFR 205.300- 205.311.

The representative label samples submitted for use were verified to meet standards and approved for use by the certification agent.

Product Process & Plant Layout: 205.272.

Product Process Flow description was complete and accurate. Equipment used to receive the materials, store, then process the product, package and final storage prior to shipping were verified. All organic production occurs only in the dedicated spaces as well as with dedicated equipment within the facility that has been assigned to O-TAC production by color coding (green). The process is simple, once the materials are in the storage tanks, the amount of natural alcohol is determined and the proper amount of surfactant is added to assist aid in diluting the content. Directly after completion of this process, sampling takes place by the laboratory on site to determine if the batch meets specification. Should the completed blending meet the requirements, then the O-TAC batch is released by Quality to the production unit where the product is then available for packaging. This was verified at the inspection. The batch production process is confirmed by the O-TAC Batch Sheet. After assembly, the blended product is piped out of the blending tank and portioned out into either 5-gallon buckets or plastic totes measuring out 275 gallons. This takes place in the production unit space on the facility. Once the product is sealed, it is labeled and coded for trace. The completed unit is then transferred to a storage area that has been assigned as dedicated within the warehouse system. Finished product shipping is done fairly soon after Quality Assurance has released the batches.

<u>NOTE</u>: All finished product is fully tested prior to farmers' use!

Pest Management: 205.271 & 205.272. An organic structural pest management program shows that prevention, mechanical and biological methods are used at the facility in compliance with standards. Documentation was requested for current substances and methods of application in use by the contractor.

Process Monitoring Programs & Organic Integrity Assurance: Reg. 205.201

An organic integrity program has been implemented and addresses the areas of potential commingling or contamination. Control points, organic handling, employee training in handling protocols, quality assurance programs and a recall system are in place. Cleaning and Sanitation protocols are in place for use and are documented. During the site visit it was noted that a written HACCP cleaning and sanitation program is in place. Documentation was submitted to support prior cleaning materials in use as well as methods for equipment cleaning Equipment in use was industrial grade. No boiler chemicals or steam in use for this system.

Packaging, storage, transport and handling were noted to meet NOP standards.

The reviewer observed no issues of commingling or contamination risks to the O-TAC product during handling, storage and production/packaging, transportation.

All containers used to pack the O-TAC product are new or never used. There are no pails or other equipment/tools that are reused in the process. For the 5 gal. pail, the pail is placed on the filling line/scale and packed via the piping system with O-TAC. The scale weights are recorded and the pail lids are placed and sealed. The label contains the lot number and each label is applied to each pail by hand. Pails are then placed on pallets where it is shrink wrapped and labeled.

The totes are placed at the filler/scale line and filled with O-TAC via the piping system until it reaches the desired weight. The tote is capped by hand securely, a tamper evident seal containing a numerical sequence is applied at the cap site for added security. Then the tote is removed by use of a forklift system and placed on pallets where they are shrink wrapped and labeled.
To aid in the trace-back an additional stamped coding is being applied to each product label to assist in maintaining product integrity and sources of materials used.

Recordkeeping: Each batch run has a sequential lot number. The lot number system is as follows:
(example)
W0613824120

Plant location	Month	Day	Year	Batch No. (Production No.)
W	06	13	8	24120

In addition to the lot number, each container has the date of production displayed as month, day year as well as other governmental required labeling.

To satisfy recordkeeping audit requirements, the following attachments are included in this review:

a) Fair Products Tote Filler Weight Sheet – *This document records the filling/packaging production sequences. The time of filling, the gross weight, the tare weight and the net weight are all recorded in addition to tamper evident seal numbers.*

b) O-TAC Batch Sheet – *This document notes step by step instructions of the records for the blending of ingredients. In addition, it lists final tank readings and all amounts of ingredients used to produce that batch.*

c) Fair Product Certificate of Analysis – *This document details specific formulations with respect to each batch produced and analysis thereof.*

d) Certificate of Analysis from CRODA – *This document presents details of each formulation of raw materials supplied to Fair Products by Croda, Inc. to include in-depth analysis of product formulations and specification characteristics.*

e) Certificate of Analysis from PT Musim Mas - *This document presents details of each formulation of raw materials supplied to Fair Products by P.T. Musim Mas. to include in-depth analysis of product formulations and specification characteristics natural alcohol product.*

Fair Products/South Atlantic Services records verified a sufficient quantity of materials controls as well as in house production requirements to be used in creating the finished product requesting review to demonstrate sufficient traceback methodology to quantify the process.

Management:

Management demonstrates a good grasp of the National Organic Program under Subpart E, 205.400, Certification as well as Subpart 205.403. Production and handling are monitored to meet Quality Assurance standards under the direct supervision of the certified entity. All regulatory, health and safety licenses were approved as well as current.

CONCLUSION:

Subject to all disclosures and items noted in this report, this operation was found to be in compliance with and adhering to the requirements necessary to comply with the organic regulations as set forth The Organic Foods Production Act, Preamble to Final Rule and Section's, 205.400-406. Notwithstanding any other items that may be needed to complete this Review, the recommendation is approval for use in an organic tobacco crop production pursuant to 7CFR Section 205.404.

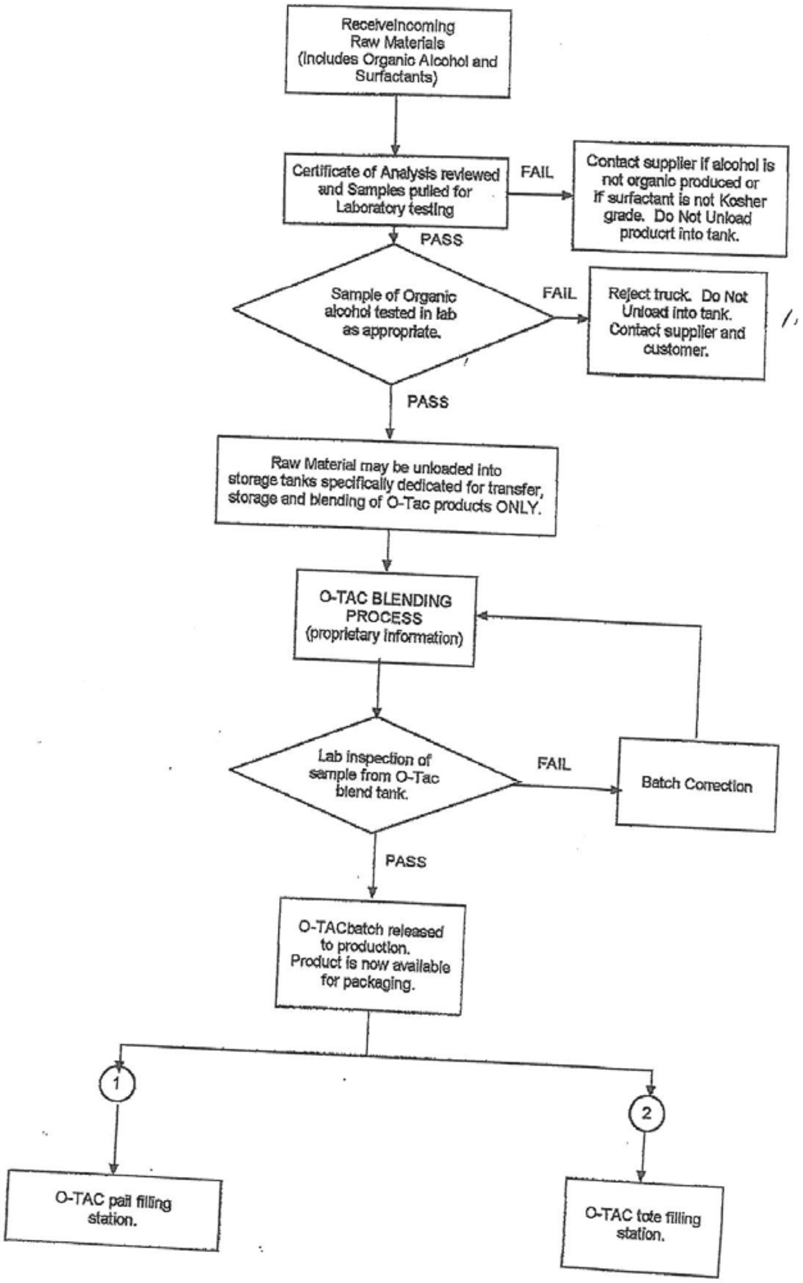
Additional attachments: O-TAC Packaging/Process Flow Chart and O-TAC Blending/Process Flow Chart

Respectfully submitted,

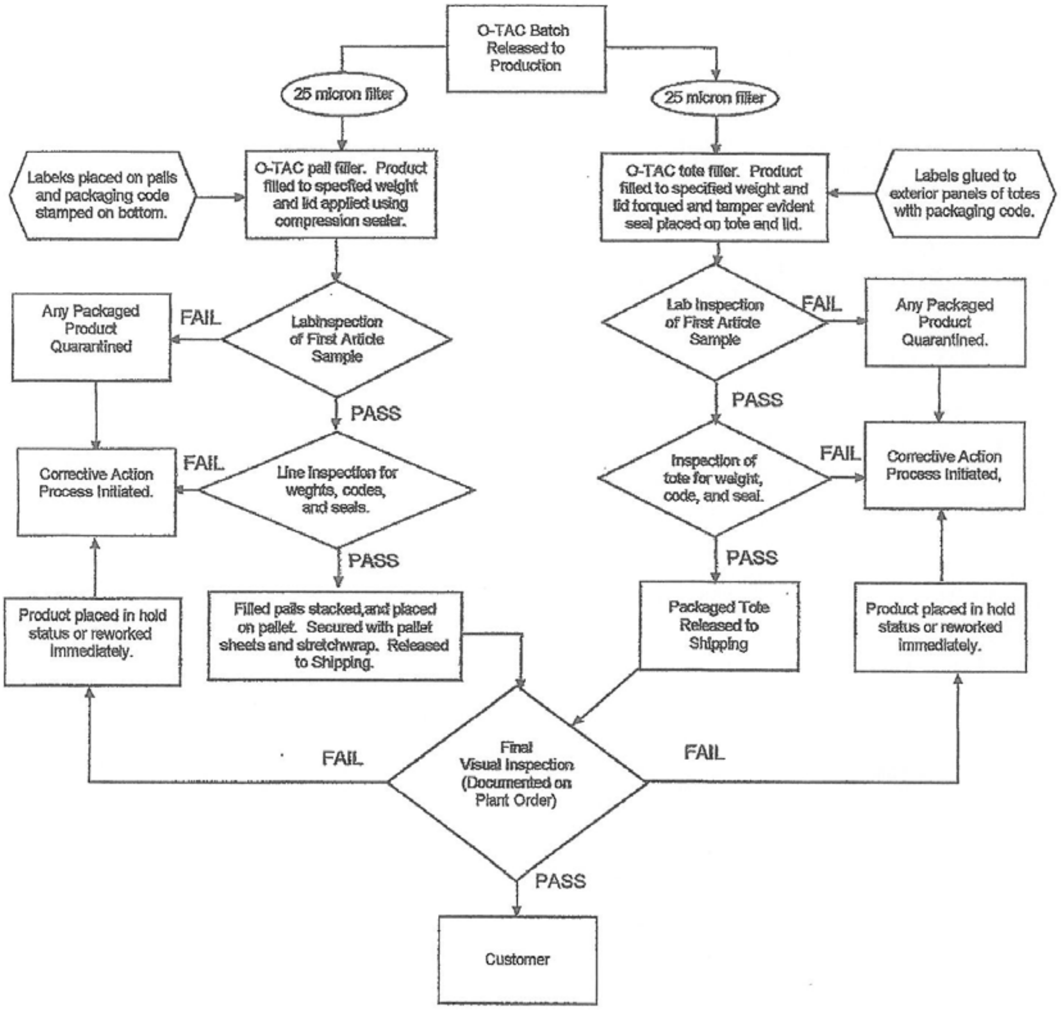
Carmen M. Pape

Carmen M. Pape
Independent Third Party Inspector & Reviewer
13847 Staytonville Road
Greenwood, Delaware 19950
302-245-3195 – carmenmaria41@outlook.com

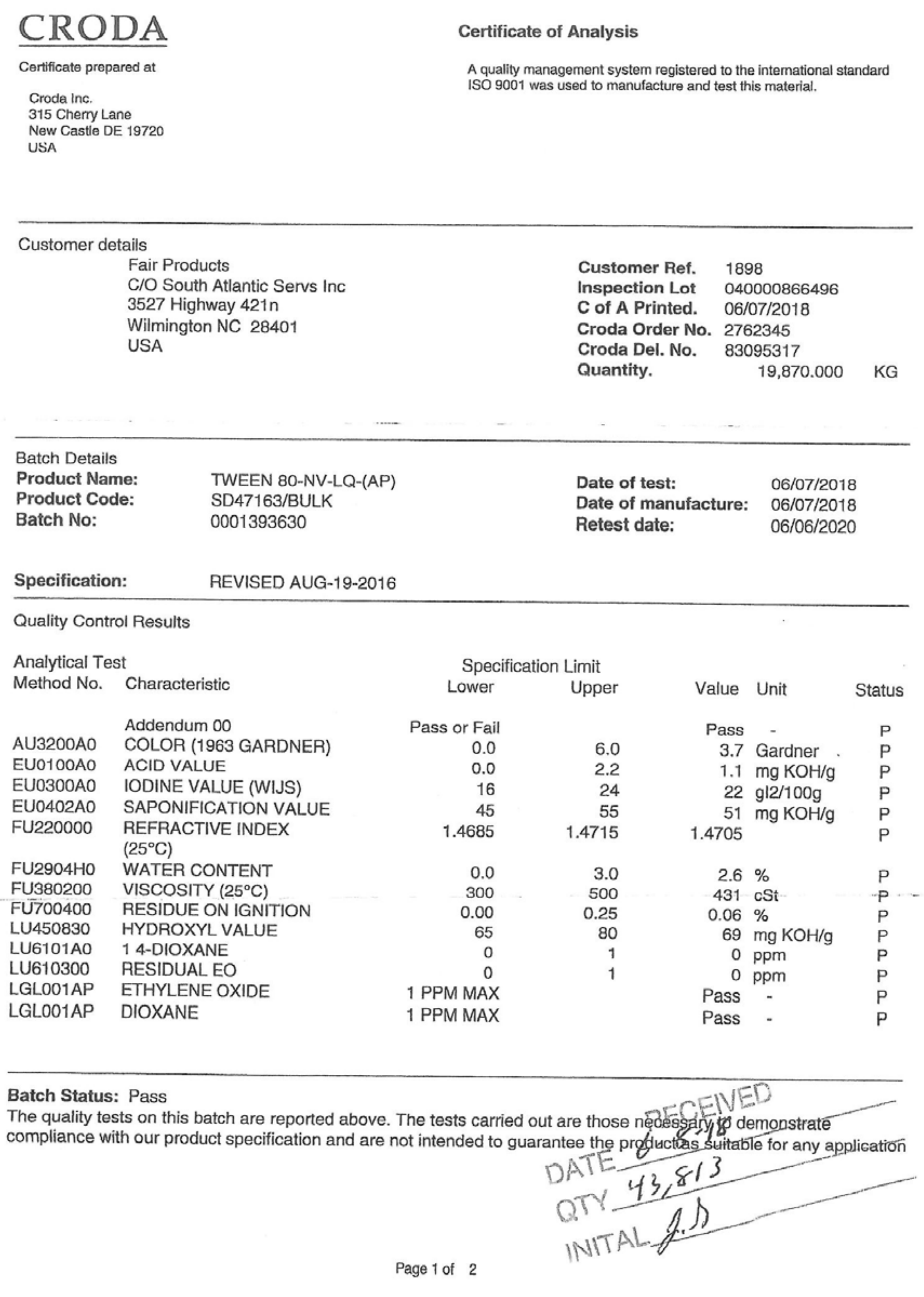
O-TAC BLENDING
Process Flow Chart



O-TAC PACKAGING
Process Flow Chart



NOTE: ALL TRANSFER LINES, PUMPS, AND HOSES USED IN THE BLENDING AND PACKAGING PROCESS OF O-TAC ARE SOLELY DEDICATED FOR THAT PURPOSE AND ARE CLEARLY MARKED THROUGHOUT THE PLANT AND PACKAGING AREAS.



CRODA

Certificate prepared at

Croda Inc.
315 Cherry Lane
New Castle DE 19720
USA

Certificate of Analysis

A quality management system registered to the international standard ISO 9001 was used to manufacture and test this material.

Customer details

Fair Products
C/O South Atlantic Servs Inc
3527 Highway 421n
Wilmington NC 28401
USA

Customer Ref. 1898
Inspection Lot 040000866496
C of A Printed. 06/07/2018
Croda Order No. 2762345
Croda Del. No. 83095317
Quantity. 19,870.000 KG

Batch Details

Product Name: TWEEN 80-NV-LQ-(AP)
Product Code: SD47163/BULK
Batch No: 0001393630

Date of test: 06/07/2018
Date of manufacture: 06/07/2018
Retest date: 06/06/2020

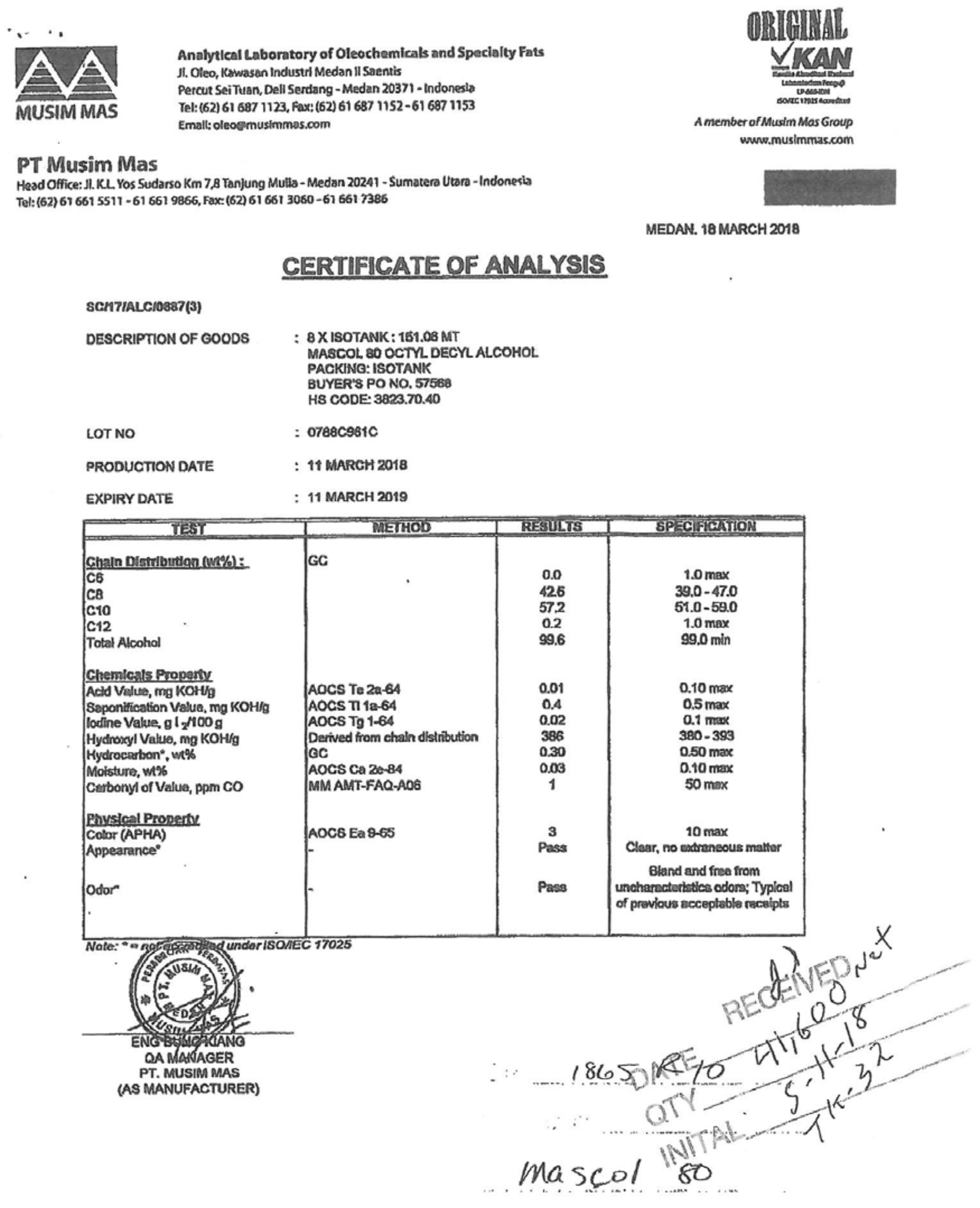
Specification: REVISED AUG-19-2016

Quality Control Results

Analytical Test Method No.	Characteristic	Specification Limit Lower	Upper	Value	Unit	Status
	Addendum 00	Pass or Fail		Pass	-	P
AU3200A0	COLOR (1963 GARDNER)	0.0	6.0	3.7	Gardner	P
EU0100A0	ACID VALUE	0.0	2.2	1.1	mg KOH/g	P
EU0300A0	IODINE VALUE (WIJS)	16	24	22	gI2/100g	P
EU0402A0	SAPONIFICATION VALUE	45	55	51	mg KOH/g	P
FU220000	REFRACTIVE INDEX (25°C)	1.4685	1.4715	1.4705		P
FU2904H0	WATER CONTENT	0.0	3.0	2.6	%	P
FU380200	VISCOSITY (25°C)	300	500	431	cSt	P
FU700400	RESIDUE ON IGNITION	0.00	0.25	0.06	%	P
LU450830	HYDROXYL VALUE	65	80	69	mg KOH/g	P
LU6101A0	1 4-DIOXANE	0	1	0	ppm	P
LU610300	RESIDUAL EO	0	1	0	ppm	P
LGL001AP	ETHYLENE OXIDE	1 PPM MAX		Pass	-	P
LGL001AP	DIOXANE	1 PPM MAX		Pass	-	P

Batch Status: Pass

The quality tests on this batch are reported above. The tests carried out are those necessary to demonstrate compliance with our product specification and are not intended to guarantee the product as suitable for any application



MUSIM MAS

Analytical Laboratory of Oleochemicals and Specialty Fats
Jl. Oleo, Kawasan Industri Medan II Saentis
Percut Sei Tuan, Deli Serdang - Medan 20371 - Indonesia
Tel: (62) 61 687 1123, Fax: (62) 61 687 1152 - 61 687 1153
Email: oleo@musimmas.com

ORIGINAL

KAN

A member of Musim Mas Group
www.musimmas.com

PT Musim Mas
Head Office: Jl. K.L. Yos Sudarso Km 7,8 Tanjung Mulia - Medan 20241 - Sumatera Utara - Indonesia
Tel: (62) 61 661 5511 - 61 661 9866, Fax: (62) 61 661 3060 - 61 661 7386

[redacted]

MEDAN. 18 MARCH 2018

CERTIFICATE OF ANALYSIS

SC/17/ALC/0887(3)

DESCRIPTION OF GOODS : 8 X ISOTANK : 151.08 MT
MASCOL 80 OCTYL DECYL ALCOHOL
PACKING: ISOTANK
BUYER'S PO NO. 57568
HS CODE: 3823.70.40

LOT NO : 0788C981C

PRODUCTION DATE : 11 MARCH 2018

EXPIRY DATE : 11 MARCH 2019

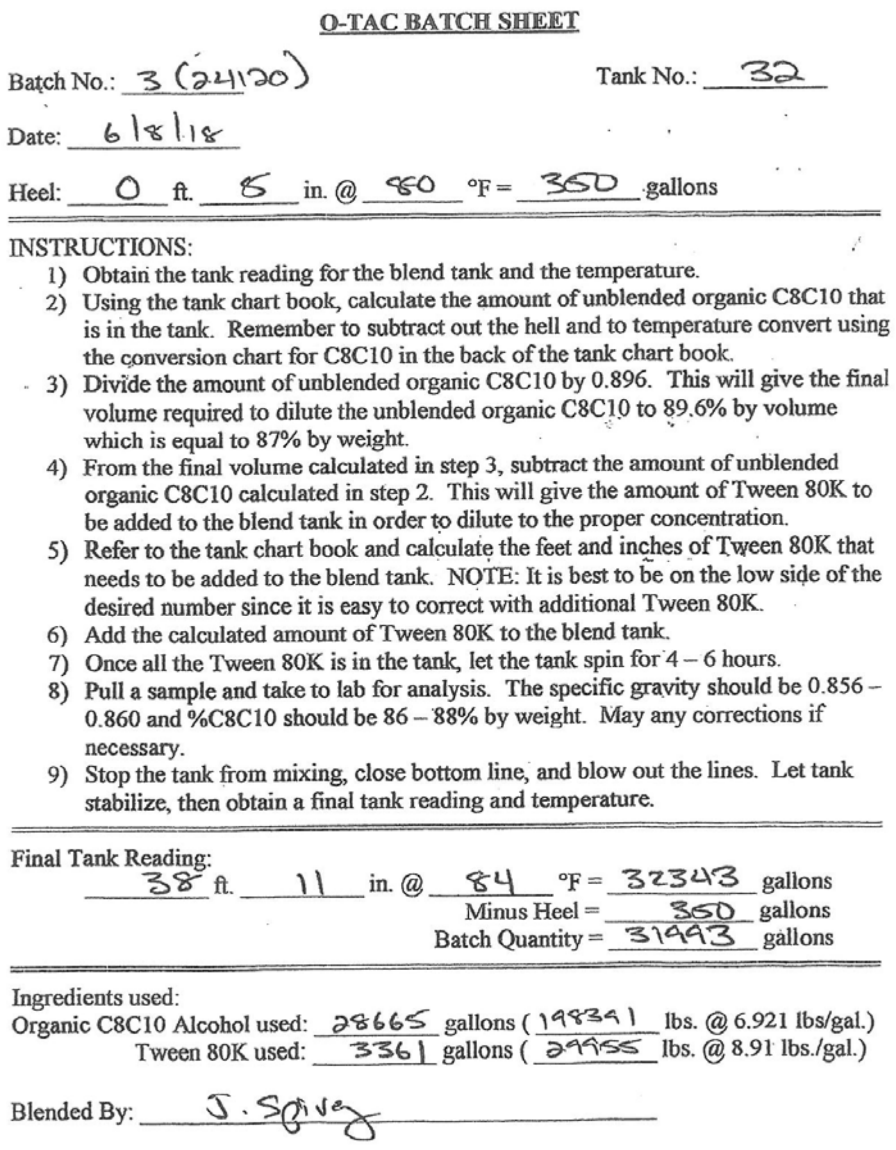
TEST	METHOD	RESULTS	SPECIFICATION
Chain Distribution (wt%) :	GC		
C6		0.0	1.0 max
C8		42.6	39.0 - 47.0
C10		57.2	51.0 - 59.0
C12		0.2	1.0 max
Total Alcohol		99.6	99.0 min
Chemicals Property			
Acid Value, mg KOH/g	AOCS Te 2a-64	0.01	0.10 max
Saponification Value, mg KOH/g	AOCS Tl 1a-64	0.4	0.5 max
Iodine Value, g I_2/100 g	AOCS Tg 1-64	0.02	0.1 max
Hydroxyl Value, mg KOH/g	Derived from chain distribution	386	380 - 393
Hydrocarbon*, wt%	GC	0.30	0.50 max
Moisture, wt%	AOCS Ca 2e-84	0.03	0.10 max
Carbonyl of Value, ppm CO	MM AMT-FAQ-A06	1	50 max
Physical Property			
Color (APHA)	AOCS Ea 9-65	3	10 max
Appearance*	-	Pass	Clear, no extraneous matter
Odor*	-	Pass	Bland and free from uncharacteristics odors; Typical of previous acceptable receipts

*Note: * = not accredited under ISO/IEC 17025*

ENG BUNG KIANG
QA MANAGER
PT. MUSIM MAS
(AS MANUFACTURER)

RECEIVED
1865 DATE 70 41,600 net
QTY 5-11-18
INITAL TK-32

Mascol 80



O-TAC BATCH SHEET

Batch No.: 3 (24120)   Tank No.: 32

Date: 6/8/18

Heel: 0 ft. 5 in. @ 80 °F = 350 gallons

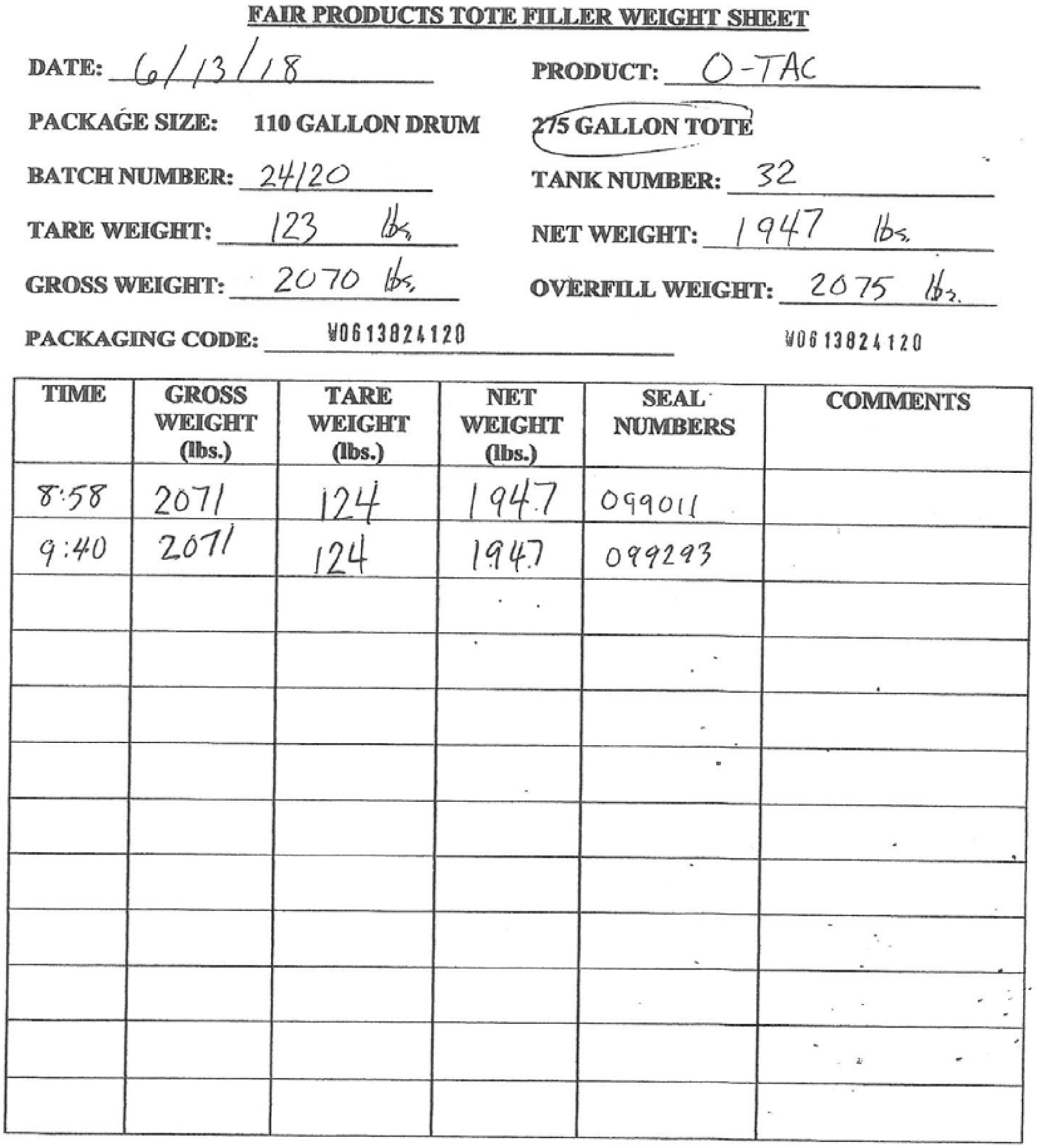
INSTRUCTIONS:

1) Obtain the tank reading for the blend tank and the temperature.
2) Using the tank chart book, calculate the amount of unblended organic C8C10 that is in the tank. Remember to subtract out the hell and to temperature convert using the conversion chart for C8C10 in the back of the tank chart book.
3) Divide the amount of unblended organic C8C10 by 0.896. This will give the final volume required to dilute the unblended organic C8C10 to 89.6% by volume which is equal to 87% by weight.
4) From the final volume calculated in step 3, subtract the amount of unblended organic C8C10 calculated in step 2. This will give the amount of Tween 80K to be added to the blend tank in order to dilute to the proper concentration.
5) Refer to the tank chart book and calculate the feet and inches of Tween 80K that needs to be added to the blend tank. NOTE: It is best to be on the low side of the desired number since it is easy to correct with additional Tween 80K.
6) Add the calculated amount of Tween 80K to the blend tank.
7) Once all the Tween 80K is in the tank, let the tank spin for 4 – 6 hours.
8) Pull a sample and take to lab for analysis. The specific gravity should be 0.856 – 0.860 and %C8C10 should be 86 – 88% by weight. May any corrections if necessary.
9) Stop the tank from mixing, close bottom line, and blow out the lines. Let tank stabilize, then obtain a final tank reading and temperature.

Final Tank Reading:
38 ft. 11 in. @ 84 °F = 32343 gallons
Minus Heel = 350 gallons
Batch Quantity = 31993 gallons

Ingredients used:
Organic C8C10 Alcohol used: 28665 gallons (198391 lbs. @ 6.921 lbs/gal.)
Tween 80K used: 3361 gallons (29955 lbs. @ 8.91 lbs./gal.)

Blended By: J. Spivey



FAIR PRODUCTS TOTE FILLER WEIGHT SHEET

DATE: 6/13/18

PRODUCT: O-TAC

PACKAGE SIZE: 110 GALLON DRUM [✓ 275 GALLON TOTE]

BATCH NUMBER: 24120

TANK NUMBER: 32

TARE WEIGHT: 123 lbs.

NET WEIGHT: 1947 lbs.

GROSS WEIGHT: 2070 lbs.

OVERFILL WEIGHT: 2075 lbs.

PACKAGING CODE: W0613824120

W0613824120

TIME	GROSS WEIGHT (lbs.)	TARE WEIGHT (lbs.)	NET WEIGHT (lbs.)	SEAL NUMBERS	COMMENTS
8:58	2071	124	1947	099011	
9:40	2071	124	1947	099293	

ITEM B.10 Physical and Chemical Properties

PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE (FATTY ALCOHOL BLEND)

Test or Study & Data point	Guideline and method	Test material purity and specification	Findings	Comments	GLP	Reference
II A 2.1.1 Melting point	830.7200 (63-5)	Technical Grade Fatty Alcohol (0.3% hexanol; 42.7% octanol; 56.7% decanol; 0.3% dodecanol)	Product is a liquid at room temperature		Y N	MRID 43127902 MRID 94313001 SASOL MSDS
II A 2.1.2 Boiling point	830-7200 (63-6)	Technical Grade Fatty Alcohol (0.3% hexanol; 42.7% octanol; 56.7% decanol; 0.3% dodecanol)	209.9°C at 763.3 mm/Hg		Y	MRID 4312790. SASOL MSDS
II A 2.2 Density	830.7300 (63-7)	0.4% hexanol 45.1% octanol 54.5% decanol	6.93 lbs/gal at 15.5°C 0.831 g/ml at 16°C		N	MRID 94313001 SASOL MSDS
II A 2.3 Vapor pressure	830.7950 (63-9)	Technical Grade Fatty Alcohol (0.3% hexanol; 42.7% octanol; 56.7% decanol; 0.3% dodecanol)	0.0423 torr; (68.4 mm Hg @ 52°C)		Y	MRID 43127903 SASOL MSDS

PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE (FATTY ALCOHOL BLEND)

Test or Study & Data point	Guideline and method	Test material purity and specification	Findings	Comments	GLP	Reference
II A 2.4.1 Physical State	830.6302 (63-2)	0.4% hexanol 45.1% octanol 54.5% decanol	Only colorless liquid		N	MRID 94313001 SASOL MSDS
II A 2.4.1 Color	830.6303 (63-3)	0.4% hexanol 45.1% octanol 54.5% decanol	Colorless liquid		N	MRID 94313001 SASOL MSDS
II A 2.4.2 Odor	830.6304 (63-4)	Technical Grade Fatty Alcohol (0.3% hexanol; 42.7% octanol; 56.7% decanol; 0.3% dodecanol)	Musty		Y	MRID 43127903 SASOL MSDS
		0.4% hexanol 45.1% octanol 54.5% decanol	Slightly Aromatic		N	MRID 94313001
II A 2.5.1 UV Spectra	830.7050	Alfol 810 Lot 1169975	The product in basic methanol shows an absorbance maximum at 204 nm		Y	MRID 47589901
II A 2.6 Solubility in water	830.7840	Technical Grade Fatty Alcohol (0.3% hexanol; 42.7% octanol; 56.7% decanol; 0.3% dodecanol)	0.0035 g/ml @ 25°C		Y	MRID 43127903 SASOL MSDS

PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE (FATTY ALCOHOL BLEND)

Test or Study & Data point	Guideline and method	Test material purity and specification	Findings	Comments	GLP	Reference
II A 2.7 Solubility in organic solvents	830.1000 (63-8)		No Data			
II A 2.8.1 n-octanol/water partition coefficient	830.7550 (63-11)	Alfol 810		Waiver requested to EPA		MRID 48100901
II A 2.9 Stability to sunlight	830.6313 (63-13)	Alfol 810		Waiver requested to EPA		MRID 48100901
II A 2.11 Flammability	830.6315 (63-15)	Alfol 810 Lot 1169975	Fire point at 105.9°C			MRID 47589901 SASOL MSDS
II A 2.13 Explodability	830.6316 (63-16)	Alfol 810 Lot 1169975		This product is not potentially explosive. Contains no nitrogen groups or explosive functional groups.	Y	MRID 47589901
II A 2.15 oxidation	830.6314 (63-14)	Alfol 810 Lot 1169975	No signs of reaction to these exposure systems: -Powdered iron -Potassium permanganate - Water -Mono-ammonium phosphate	Product contains no oxidizing or reducing agents.	Y	MRID 47589901

PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE (FATTY ALCOHOL BLEND)

Test or Study & Data point	**Guideline and method**	**Test material purity and specification**	**Findings**	**Comments**	**GLP**	**Reference**
II A 2.16 pH	830.7000 (63-12)	Technical Grade Fatty Alcohol (0.3% hexanol; 42.7% octanol; 56.7% decanol; 0.3% dodecanol)	pH = 6.17		Y	MRID 43127903
II A 2.17.1 Storage Stability	830.6317 (63-17)	Technical Grade Fatty Alcohols Lot No. 1169975 Alfol 810	No changes were noted for the test substance after 3,6,9 and 12 months of storage at Room Temperature (23°C)		Y	MRID 47589901
II A 2.17.2 Storage Stability (Temperature, metals)	830.6313 (63-13)	98.83% Fatty Alcohol Blend Lot ONT-0324	Fatty Alcohols remain stable for 14 days at room temperature and 54+/-2°C alone and when exposed to stainless steel, alumimum, alumimum acetate and iron. A decrease in the assay when the test substance was exposed to iron acetate at both room and elevated temperatures.		Y	MRID 48100901 MRID 47972901

PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE

(FATTY ALCOHOL BLEND)

Test or Study & Data point	**Guideline and method**	**Test material purity and specification**	**Findings**	**Comments**	**GLP**	**Reference**
II A 2 Corrosion Characteristics	830.6320 (63-20)	Technical Grade Fatty Alcohols Lot No. 1169975 Alfol 810	After 12 months at Room Temperature, no chemical or physical effects were noted on the commercial packaging material, HDPE		Y	MRID 47589901 MRID 47972901
II A 2 Viscosity	830.7100	Alfol 810 Lot 1169975	13.5 $mm^2/5$ at 22°C		Y	MRID 47589901
II A 2 Miscibility	830.6319 (63-19)		The product is not an emulsifiable concentrate and is not to be diluted with petroleum products			Fatty Alcohol Task Force Citations 6/4/08
II A 2 Dielectric Breakdown Voltage	830.6321 (63-21)		This product is not labeled to be used around electrical equipment			Fatty Alcohol Task Force Citations 6/4/08

REFERENCES

IDENTITY OF THE ACTIVE SUBSTANCE:

Author(s)	EPA Guideline Number	Year	Title	Data Protection Claimed	Owner	MRID#
Jacobson, S.	830.7200	1994	Determination of the Chemical Characteristics of a Fatty Alcohol Blend: Product Chemistry: Lab Project Number: FATF-9303C. Unpublished study prepared by Compliance Services International. 125 p.	Y	Fatty Alcohol Task Force	43127903
Jacobson, S.	830.7200	1994	Determination of the Chemical Characteristics of a Fatty Alcohol Blend: Product Chemistry: Lab Project Number: FATF-9303C. Unpublished study prepared by Compliance Services International. 125 p.	Y	Fatty Alcohol Task Force	43127903
Jacobson, S.	830.7200	1994	Determination of the Chemical Characteristics of a Fatty Alcohol Blend: Product Chemistry: Lab Project Number FATF-9301. Unpublished study prepared by Compliance Services International. 34p.	Y	Fatty Alcohol Task Force	43127901
Jacobson, S.	830.7200	1994	Determination of the Chemical Characteristics of a Fatty Alcohol Blend: Product Chemistry: Lab Project Number FATF-9302. Unpublished study prepared by Compliance Services International. 126p.	Y	Fatty Alcohol Task Force	43127902
Jacobson, S	830.7300	1990	Fatty Alcohol Task Force Phase 3 Summary of MRID: 00056022 and Related MRIDs 00056023, 00056025, 00056026, 00056027, 00056028, 00056029, 00056030. Product Chemistry: Fatty Alcohols. 20p.	Y	Fatty Alcohol Task Force	94313001
Sinning, D. J.	830.6317 830.6313	2/2010	Physical and Chemical Characteristic of Technical Grade Fatty alcohols: Storage Stability and Corrosion Characteristics. Study Number 4080-02; Case Consulting Laboratories, Inc. 2/3/2010, 23 p.	Y	Fatty Alcohol Task Force	To be assigned by EPA

a. **Chemical interactions with other substances, especially substances usual in organic production:**

None known

b. **Toxicity and environmental persistence's:**

FATE AND BEHAVIOR IN THE ENVIRONMENT:

There are no available studies on the environmental fate of the fatty alcohol blend/ aliphatic alcohols. It is important to remember that active substance, fatty alcohol blend, is classified and approved as food additives by the US food and Drug Administration. The following has been reproduced from EPA's document "Registrations Eligibility Decision for Aliphatic Alcohols, Case No. 4-004, March 2007, EPA 738-R-07-004.

1. Environmental Fate and Transport

Because environmental fate data are not available, physical and chemical properties for the aliphatic alcohols were estimated by Quantitative Structure-Activity Relationships (QSAR) using EPISuite v 3.21 (Estimation Programs Interface for Windows (EPIWIN)). The estimated properties of 1-octanol, 1-decanol and 1-dodecanol differ somewhat, due to the different lengths (i.e. number of carbons) in their straight, saturated carbon chains. As suggested by their common names, 1-octanol has 8 carbons in its chain, 1-decanol has 10 carbons, and 1 –dodecanol has 12 carbons.

In spite of these small differences, the expected behavior of these aliphatic alcohols in the environment is generally similar. The major route of dissipation in the field for these chemicals is likely to be volatilization. The volatility half-lives for 1-octanol and 1-decanol were estimated using the Dow Method described in the *Handbook of Chemical Property Estimation Methods* by Lyman, Reehl and Rosenblatt. The half-lives for volatility from soil for 1-octanol and 1-decanol were estimated to be 3.5 minutes and 1 minute, respectively. 1-dodecanol would likely volatilize even more quickly, but the half-life was not estimated, since volatility from pheromone traps is the known route of dissipation.

There is some uncertainty about the rate of volatility of 1-octanol and 1-decanol from plant surfaces, since aliphatic alcohols are hydrophobic and, therefore, have affinity for the waxy surfaces of plants. However, these volatility half-lives suggest that the aliphatic alcohols will not be available long to expose non-target terrestrial animals, nor to be transported to surface water bodies in runoff. Residues of 1-dodecanol are not expected on plants or in soil, since they are dispersed in the air from pheromone traps, and then degraded by photolysis. The ecological risk assessment concluded that except for terrestrial insects, which are the target for the pheromone use of 1-dodecanol, "environmental exposures resulting from this use are likely negligible." The risk assessment for this use was therefore qualitative.

Additional estimation of environmental fate parameters obtained from EPISuite provides a basic set of data to perform a screening-level environmental risk assessment. The model indicates that aliphatic alcohols have a moderate tendency to bind to soils. The portion of applied chemical that binds to the soil, rather than volatilizing, will be subject to biodegradation, with estimated half-lives for1-octanol and 1-decanol of 2.3 days. The portion of applied chemical that does volatilize is estimated to degrade in the air by reaction with hydroxyl radicals with half-lives of about 10 hours.

As mentioned above, dissipation via volatilization will greatly reduce the amount of aliphatic alcohols reaching surface-water bodies, and aliphatic alcohols will volatilize from water as well as soil. However, the fraction that does reach surface water will not be degraded by hydrolysis. These alcohols have the potential to bioaccumulate in fish, but the rates of uptake, metabolism, and depuration, as well as the nature of metabolites, are not known. However, the magnitude of the bioconcentration factors (BCF) suggests a low potential to bioconcentrate.

EPISuite does not provide information on the rates of formation/decline of product, the nature and relative amounts of transformation products, and their distribution in soil/sediment-water- air. Therefore, the specific nature and persistence of potential biotransformation products (primary biodegradation) are not known. However, the ultimate biotransformation products of the aliphatic alcohols are water and carbon dioxide.

2. Ecological Risk Assessment

The Agency uses a pesticide's use profile, exposure data, and toxicity information to determine risk estimates to non-target terrestrial and aquatic organisms. Estimated environmental concentrations (BECs) are used to calculate risk quotients (RQs). EECs are based on the maximum application rate(s) which would potentially yield the greatest exposure. An RQ is derived by dividing the EEC by a single estimate of toxicity. The Agency then compares an RQ to its Level of Concern (LOC) to determine if exposure to the aliphatic alcohols could potentially pose a risk to non-target organisms (RQs that exceed the LOC indicate potential risk).Table 5 outlines LOCs, and the Agency's corresponding risk presumptions.

Table 5 -Agency level of Concerns and Risk Presumptions

Risk Presumption	LOC Terrestrial Animals	LOC Aquatic Animals	LOC Plants
Acute Risk – there is a potential for acute risk	0.5	0.5	1
Acute Endangered Species – endangered species may be adversely affected	0.1	0.05	1
Chronic Risk – there is potential for chronic risk.	1	1	N/A

a. Exposure to Aquatic Organisms

The Agency ran a number of exposure modeling simulations to derive expected environmental concentrations of aliphatic alcohols in surface water. The Agency first ran the Tier I GENEEC model, which resulted in exceedences of the endangered species level of concern (LOC) for freshwater fish and estuarine/marine invertebrates for some application scenarios. However, these simulations did not consider the volatilization of aliphatic alcohols from soil, and each thereby overestimated potential exposure.

Although GENEEC is not designed to consider volatility from soil directly, the Agency used an indirect method to consider volatility with the GENEEC model and to refine the aquatic exposure assessment. As described above, the volatility half-lives for the aliphatic alcohols were estimated using the Dow Method described in the *Handbook of Chemical Property Estimation Methods* (Lyman, et aI., 1982). The half-lives for volatility from soil for 1-octanol and 1-decanol were estimated to be 3.5 minutes and 1 minute, respectively. Such short volatility half-lives mean that little pesticide will remain by the time a runoff event occurred, unless rainfall began immediately after application.

To simulate this scenario using GENEEC, the Agency determined the amount of 1-octanol or 1-decanol that would remain in the field 3 to 4 minutes after application at the maximum rates allowed on the label. GENEEC was then run in the standard fashion, but with this "effective application rate." Even though this was done using estimated volatility half-lives on the order of a couple of minutes, the resulting EECs are still considered upper-bound.

GENEEC does not simulate a rainfall event until two days after application; if rainfall does not occur until two days after actual application of 1-octanol or 1-decanol, there could be very little product remaining to be subject to transport in runoff. For this reason, the simulations considered only a single application, although aliphatic alcohols can be used more than once within a single growing season.

b. Toxicity to Aquatic Organisms

Registrant-submitted data and open literature studies suggest that the aliphatic alcohols are "slightly" to "moderately" toxic to freshwater fish. Although the data base is not complete for all compounds in the aliphatic alcohol registration case, there are adequate data to assess the acute risk to freshwater fish. Although there are no registrant-submitted acute toxicity data available for estuarine/marine fish, data from the open literature provided the information to assess the acute risks of aliphatic alcohols to these organisms. The relevant study from the open literature indicates that 1-octanol is "slightly" toxic and 1 -decanol is "moderately" toxic to estuarine/marine fish.

No chronic toxicity guideline studies exist for any of the aliphatic alcohols. However, chronic data for freshwater fish from the open literature on 1-octanol provide an endpoint which the Agency used to calculate RQs. Chronic toxicity data for aquatic invertebrates on the aliphatic alcohols were also drawn from the open literature. The Agency used a chronic no observed adverse effect concentration (NOAEC) of I mg/L for reproductive effects for 1-octanol. The Agency notes that chronic toxicity data on 1-decanol for aquatic invertebrates would reduce the uncertainty posed by the lack of these data. A summary of all toxicity endpoints is presented below in Table 6.

Table 6 - Toxicity Reference Values Used to Calculate RQs for Aliphatic Alcohols

Taxonomic Group	**Assessment Endpoint**	**1-Octanol**	**1-Decanol**
		Species/ Toxicity Endpoint	**Species/Toxicity Endpoint**
Freshwater Fish	Survival	Fathead Minnow Acute LC_{50}=12.2 mg/L	Fathead minnow Acute LC_{50}=2.3 mg/L
	Reproduction, Growth	Fathead minnow NOAEC=0.75 mg/L	No data available
Freshwater Invertebrates	Survival	Water flea Acute LC_{50}=4.16 mg/L	Water flea Acute LC_{50}=6.5 mg/L
	Reproduction, Growth	Water flea Chronic NOAEC=1 mg/L	No data available
Estuarine/marine fish	Survival	Bleak Acute LC_{50}=15 mg/L	Bleak Acute LC_{50}=7.2 mg/L
	Reproduction, Growth	No data available	No data available
Estuarine/marine Invertebrates	Survival	Harpacticoid copepod LC_{50}=58 mg/L	Harpacticoid copepod LC_{50}=4 mg/L
	Reproduction, Growth	No data available	No data available
Aquatic Plants	Survival, Growth	*Scenedesmus subspicatus* EC_{50}-6.5 mg/L; EC_{10}-2.8 mg/L	No data available

LC_{50} - Median Lethal Concentration, statistically derived single concentration that can be expected to cause death In 50% of the test animals; EC_{50} - Median Effect Concentration, statistically derived single concentration that can be expected to cause an adverse effect in 50% of the test animals or plants; EC_{10} - statistically derived single concentration that can be expected to cause an adverse effect in 10% of the test animals or plants; NOAEC – no observed adverse effect concentration.

c. Risk to Aquatic Organisms

Based on the refined surface water EECs and the available ecotoxicity data for 1-octanol and 1 -decanol, RQs for aquatic animals do not exceed acute LOCs. In addition, although chronic toxicity data are available for 1-octanol, but not 1-decanol, aliphatic alcohols do not appear to pose a chronic risk to freshwater aquatic animals. No chronic toxicity data are available for estuarine/marine fish and invertebrates. In spite of these data gaps, the Agency does not anticipate chronic risk to estuarine marine fish and invertebrates. As described above, little 1-octanol or 1 -decanol would likely be available for transport in runoff if a significant rain event did not occur within a few hours of application. Estimated RQs for 1-decanol and 1-octanol are summarized in Tables 7 - 10 below.

Table 7- Acute and Chronic RQs for Freshwater Fish

Chemical	Effective Application Rate (lbs a.i./acre)	Peak EEC (µg/L)	Toxicity Value (µg/L)	Acute RQ	60-Max Average EEC (µg/L)	Chronic RQ
1-Decanol	1.95, 1 application	57	LC_{50}=2300 NOAEC-nd	0.02	13	nd
1-Octanol	4.4,1 application	140	LC_{50}=12200 NOAEC=750	0.01	29	<1

Table 8 - Acute and Chronic RQ's for Estuarine/Marine Fish

Chemical	Effective Application Rate (lbs. a.i./acre)	Peak EEC (µg/L)	Toxicity Value (µg/L)	Acute RQ	60-Max Average EEC (µg/L)	Chronic RQ
1-Decanol	1.95, 1 application	57	LC_{50}=7200 NOAEC-nd	<0.01	13	nd
1-Octanol	4.4,1 application	140	LC_{50}=15000 NOAEC=nd	<0.01	29	nd

Table 9 - Acute and Chronic RQs for Freshwater Invertebrates

Chemical	Effective Application Rate (lbs a.i./acre)	Peak EEC (µg/L)	Toxicity Value (µg/L)	Acute RQ	60-Max Average EEC (µg/L)	Chronic RQ
1-Decanol	1.95, 1 application	57	LC_{50}=6500 NOAEC-nd	<0.01	29	nd
1-Octanol	4.4,1 application	140	LC_{50}= 4160 NOAEC=1000	0.03	70	<1

Table 10 - Acute and Chronic RQs for Estuarine/Marine Invertebrates

Chemical	Effective Application Rate (lbs a.i./acre)	Peak EEC (µg/L)	Toxicity Value (µg/L)	Acute RQ	60-Max Average EEC (µg/L)	Chronic RQ
1-Decanol	1.95, 1 application	57	LC_{50}=4000 NOAEC-nd	0.01	29	nd
1-Octanol	4.4,1 application	140	LC_{50}=58000 NOAEC=nd	<0.01	70	nd

nd no data

Aquatic plant toxicity data from open literature were only available for 1-octanol. Based on these data, the acute RQs for aquatic plants do not exceed the Agency's acute and endangered given that the NOAEC for 1-octanol is unknown, and no aquatic phytotoxicity data are available for 1-decanol. The NOAEC is used to calculate an RQ to evaluate potential risk to endangered species. Because the NOAEC was not established, the EC_{10} for 1-octanol was used. Since the LOC for endangered aquatic plants is 1.0, and the RQ derived using the EC_{10} is 0.05, the NOAEC would have to be at least 20 times lower than the EC_{10} for the Agency to have an endangered species concern for aquatic plants.

Based on the analysis of the volatility of the aliphatic alcohols, aquatic exposures resulting from the labeled use of 1-decanol and 1-octanol are unlikely to reach concentrations that exceed the Agency's LOC. As a result, the value of additional aquatic plant studies for the aliphatic alcohols is low.

Table 11- Risk to Aquatic PIants

Chemical	Effective Application Rate (lbs a.i./acre)	Peak EEC (µg/L)	Toxicity Value (µg/L)	Acute RQ
1-Octanol	4.4,1 application	140	LC_{50}=6500 EC_{10}=2800	0.02 0.05
1-Decanol	1.95, 1 application	57	No data	----

d. Exposure, Toxicity and Risk to Terrestrial Organisms

Birds

Available toxicity data indicate that the aliphatic alcohols are categorized as "practically non-toxic" to birds on acute oral and dietary bases. Acute risks to birds were not quantified, because no discreet median lethal doses or concentrations were established in the acute oral and dietary studies. An acute dietary study from the open literature reported a dietary LC_{50} for bantam chickens of 201,000 ppm (100% 1-decanol). This level is more than 20 times greater than the highest predicted dietary exposure level (~ 10,000 ppm). Therefore, the Agency concludes that the aliphatic alcohols do not pose an acute risk to birds. No avian chronic toxicity studies were available for any of the aliphatic alcohols and, therefore, the Agency cannot directly assess the potential chronic risk to avian species. However, since 1) the aliphatic alcohols are not acutely toxic to birds at doses many times higher than expected exposure, 2) the volatility of the aliphatic alcohols makes chronic exposure unlikely, with EECs dropping more than an order of magnitude within 30 minutes, 3) the aliphatic alcohols assessed are listed as food additives and are "Generally Recognized as Safe" (GRAS) by the U.S. Food and Drug Administration[1], and 4) a mammalian chronic toxicity study indicates the aliphatic alcohols are not chronically toxic to mammals, the Agency does not expect a chronic risk to birds, and will not require chronic avian toxicity studies at this time.

Mammals

Acute oral mammalian toxicity data indicate that the aliphatic alcohols are "practically non-toxic" to mammals on an acute oral basis. Four studies performed with laboratory rats did not result in LC_{50} endpoints with which RQs could be calculated. The Agency concludes that aliphatic alcohols do not pose an acute dietary risk to mammals.

In the single chronic mammalian developmental toxicity study, which used a 1- decanol / 1-octanol blend, no chronic effects were observed in laboratory rats, even at the maximum tested dose of 957 mg/kg bw/day. It is unknown if the predicted exposures approach the level at which effects may occur since no LOAEC was identified in the chronic study. However, the Agency does not anticipate chronic risk to mammals, considering the volatility of the aliphatic alcohols, and the acceptance of these chemicals as food additives, as described above.

Terrestrial Insects

Available toxicity data indicate that aliphatic alcohols are "practically non-toxic" to honey bees (acute contact $LD_{50} > 25$ µg/bee). However, given that aliphatic alcohols can be used as Lepidopteran sex inhibitors, there is a potential for sublethal (e.g., reproductive) effects on non-target Lepidopterans, such as butterflies. This potential effect cannot be quantified at this time.

Terrestrial Plants

Tier-I terrestrial plant seedling emergence study data suggest a fatty alcohol blend (1-decanol and 1-octanol) is not toxic to most plants at the maximum rate tested (18.03 Ibs ai/A). An EC_{25} could not be established for tested species, although lesser effects were observed in cucumbers, carrots and tomatoes. Therefore, the Agency did not calculate RQs based on seedling emergence effects.

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[1] http://vm.cfsan.fda.gov/- dms/eafus.html

EC_{25} values and related no-effect levels were established for two (corn and cucumber) of 10 crop plants tested in a submitted vegetative vigor study. The Agency used these endpoints in the TerrPlant model to calculate RQs (Table 12). All were below the Agency's LOC of 1.

Table 12 - Terrestrial Plant Vegetative Vigor RQs from Drift only for Terrestrial Plants*

Class of Terrestrial Plant	Monocot	Dicot
Non-endangered species	0.02	0.01
Endangered species	0.19	0.36
*based on vegetative vigor monocot NOAEL=1.12 lbs a.i/A, EC_{25}=9.02 lbsa i./A; dicot NOAEL=0.58 lbs a.i./A EC_{25}=14.8 lbs a.i. /A (MRIDs 42514701,43379602)		

e. Adverse Ecological Incidents

There are currently no adverse ecological incidents listed in the Ecological Incident Information System (EIIS) that are associated with the aliphatic alcohols.

f. Endangered Species

Based upon the screening-level assessment conducted on aliphatic alcohols, the Agency has not definitively identified exceedences of endangered species LOCs for direct effects to non-target animals or plants. Acute RQs did not exceed endangered species LOCs for birds, mammals, terrestrial plants, freshwater fish and invertebrates, or estuarine/marine fish and invertebrates. Chronic data were not available for birds and estuarine/marine fish and invertebrates. As described above, the Agency believes that the volatility and low toxicity in

available acute and chronic toxicity studies for mammals and freshwater animals suggest that chronic risk to birds and estuarine/marine animals is unlikely. However, because the toxicity data are not available, the Agency cannot completely preclude risk to listed birds and estuarine/marine animals at this time. Similarly, since a no-effect level was not determined for aquatic plants, the Agency cannot preclude direct effects on these organisms, although exposure is expected to be negligible.

The Agency considers a potential for not only direct effects, but also adverse indirect effects to listed species that rely on other affected organisms. Because direct effects to aquatic plants cannot be precluded, indirect effects to listed aquatic species which rely on aquatic plants can also not be dismissed. Similarly, indirect effects to terrestrial plants and animals cannot be precluded because of potential reproductive effects of aliphatic alcohols to some terrestrial insects.

Table 13 - Potential Listed Species Risks Associated with Direct or Indirect Effects Due to Applications of Aliphatic Alcohols as Shoot inhibitors on Tobacco.

	Direct Effects		
Listed Taxon	**Acute**	**Chronic**	**Indirect Effects to Endangered Species**
Terrestrial and semi-aquatic plants-monocots	No	N/A	Possible
Terrestrial and semi-aquatic plants-dicots	No	N/A	Possible
Birds	No	N/A	Possible
Terrestrial –phase amphibians	No	No Data	Possible
Reptiles	No	No Data	Possible
Mammals	No	No Data	Possible
Aquatic non=vascular plants*	Insufficient data	N/A	N/A
Aquatic vascular plants	Insufficient data	N/A	N/A
Freshwater fish	No	No	Possible
Aquatic-phase amphibians	No	No	Possible
Freshwater crustaceans	No	No	Possible
Mollusks	No	N/A	Possible
Marine/ estuarine fish	No	No Data	Possible
Marine/estuarine crustaceans	No	No Data	Possible

• At the present time, no aquatic non-vascular plants are included In Federal listings of threatened and endangered species. The taxonomic group is included here for the purposes of evaluating potential contributions to indirect effects to other taxa and as a record of exceedances should future listings of non-vascular aquatic plants warrant additional evaluation of Federal actions.

Further analysis regarding the overlap of individual species with each use site is required prior to determining the likelihood of potential impact to listed species. At the screening level, this analysis is accomplished using the Location of Crops and Threatened and Endangered Species (LOCATES) data base, which uses location information for listed species at the county level and compares it to agricultural census data for crop production at the same county level of resolution. The ecological risk assessment includes a complete listing of aquatic plants, birds, reptiles, terrestrial-phase amphibians, mammals, and terrestrial invertebrates associated with the States where the aliphatic alcohols are use as a plant growth regulator on tobacco.

SUPPLEMENTAL INFORMATION:

A monograph entitled “Literature Review on Fatty Alcohol Compounds” (MRID 42135801) prepared by B.D. McGaughey of Compliance Services International provides additional information pertaining to the behavior of fatty alcohols in the environment. The areas pertaining to the following Data Requirement for EPA Pesticide Guidelines were addressed.

OPP	**GUIDELINE NUMBER**	**STUDY Chemical Identity**
160-5	Form 8570-4	Chemical Identity
161-1	835.2120	Hydrolysis
161-2	835.2240	Photodegradation – Water
161-3	835-2410	Soil photolysis
162-1	835.4100	Aerobic Soil Degradation
162.3	835.4400	Anaerobic Aquatic Degradation
163-1	835.1230	Leaching , Adsorption Desorption
163-1	835.1240	
164-1	835.6100	Terrestrial Field Dissipation
165-4	850.1730	Bioaccumulation in Fish

The conclusions reached as a result of this study/ literature review were as follows:

OPP Guideline Number 160-5, OPPTS (form 8570-4), OECD data point (II A 1.10), ***Chemical Identity***: Normal fatty alcohols are considered chemically “inert” and are precursors to fatty acids. Their production and manufacture yields a relatively pure product mixture, depending upon the “cut” desired. The C_6-C_{12} alcohols used in tobacco sucker control agents would be expected to contain no unusual or high levels of impurities.

OPP Guideline Number 161-1, OPPTS (835.2120), OECD data point (II A 7.5) ***Hydrolysis:*** Hydrolysis is not a major pathway of degradation for C_6-C_{12} alcohols.

OPP Guideline Number 161-2, OPPTS (835.2240), OECD data point (II A 7.6) ***Photodegradation in Water:*** Photolysis of C_6-C_{12} n-alcohols in water would not be expected to occur.

OPP Guideline Number 161-3, OPPTS (835.2410), OECD data point (II A 7.1.3) ***Photodegradation in Soil:*** Photolysis of C_6-C_{12} n-alcohols in soil would not be expected to occur.

OPP Guideline Number 162-1, OPPTS (835.4100), OECD data point (II A 7.1.1***) Aerobic Soil Metabolism:*** Aerobic soil metabolism is the major degradation pathway for C_6-C_{12} n-alcohols. Breakdown or assimilation by microbial organisms is rapid and complete. Half-lives may be as short as a matter of hours, and would not be expected to exceed 3 to 5 days.

OPP Guideline Number 162-3, OPPTS (835.4400), OECD data point (II A 7.8.2) ***Anaerobic Aquatic Metabolism:*** Anaerobic aquatic metabolism is similar to other microbial metabolism pathways for C_6-C_{12} n-alcohols. End products may differ due to individual organism output, but products will be natural components of the aquatic system. Breakdown or assimilation by microbial organisms is rapid and complete. Half-lives may be as short as a matter of hours and would not be expected to exceed on day.

OPP Guideline number 163-1, OPPTS (835.1230, 835.1240); OECD data point (II A7.4.1, II A 7.4.3) ***Leaching/adsorption/desorption:*** C_6-C_{12} fatty alcohols strongly adsorb to soil and would not be expected to move through the soil column. Desorption is expected to be minimal.

OPP Guideline Number 164-1, OPPTS (835.6100), OECD data point(II A 7.3.1) ***Terrestrial Field Dissipation:*** Dissipation of C_6-C_{12} fatty alcohols under field rates and conditions is rapid and complete. Half-lives as short as a matter of hours could be possible. Half-lives would not be expected to exceed 3 to 5 days.

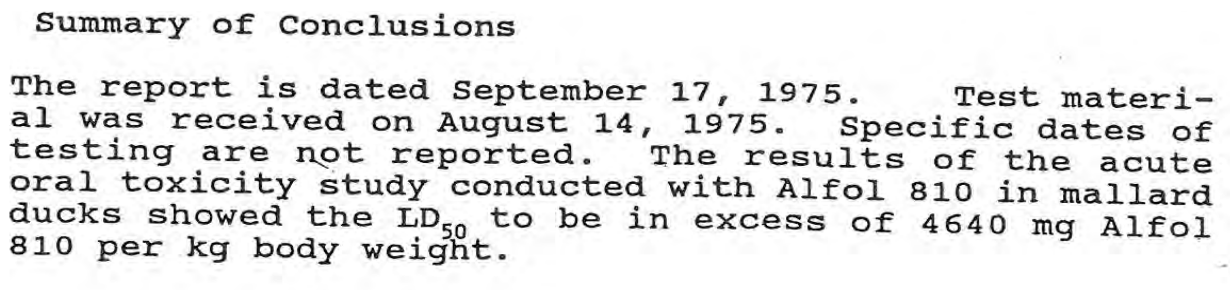
OPP Guideline number 165-4, OPPTS (835.1730), OECD data point (II A 8.2.6.1) ***Bioaccumulation in Fish:*** C_6-C_{12} fatty alcohols will not bioaccumulate in fish.

REFERENCES
FATE AND BEHAVIOR IN THE ENVIRONMENT:

Author(s)	EPA Guideline Number	Year	Title	Data Protection Claimed	Owner	MRID#
EPA		3/2007	Reregistration Eligibility Decision for Aliphatic Alcohols, United States Environmental Protection Agency; Document EPA 738-R-07-004	NO	EPA	NONE
McGaughey, B.	835.2120 835.2240 835.2410 835.4100 835.4400 835.1230 835.1240 835.6100 835.1730	1991	Literature Review on Fatty Alcohol Compounds: Lab Project Number: FATF-9101; Unpublished Study Prepared by Compliance Services International. November 15, 1991, 60 p.	Y	Fatty Alcohol Task Force	42135801

c. Environmental impact from its use or manufacture:

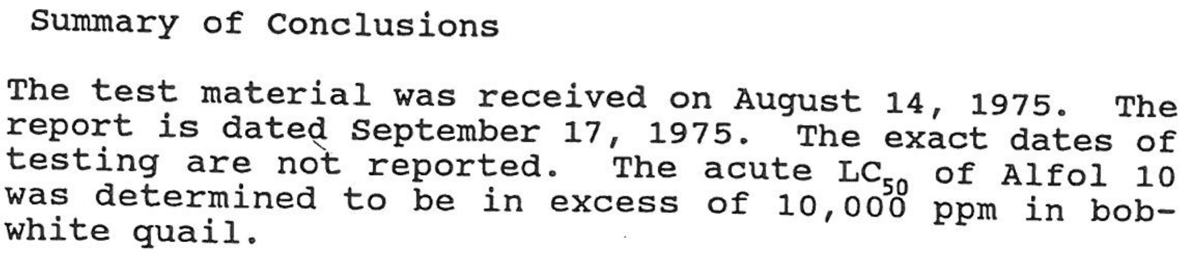
Acute Oral Toxicity to Quail, Mallard Duck



Summary of Conclusions

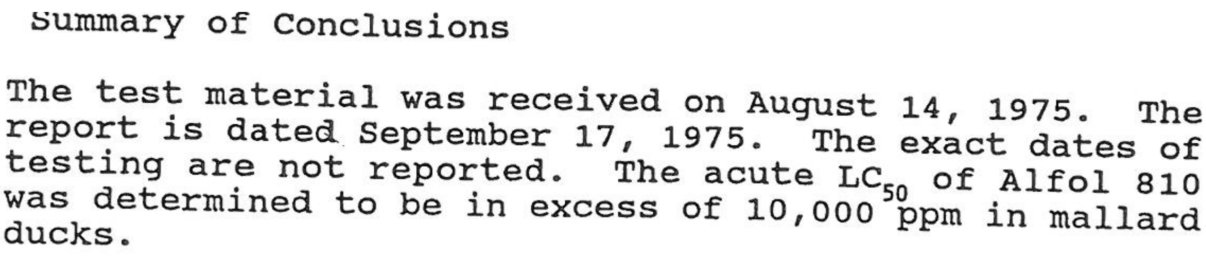
The report is dated September 17, 1975. Test material was received on August 14, 1975. Specific dates of testing are not reported. The results of the acute oral toxicity study conducted with Alfol 810 in mallard ducks showed the LD_{50} to be in excess of 4640 mg Alfol 810 per kg body weight.

Avain dietary Toxicity in Quail or Mallard Duck



Summary of Conclusions

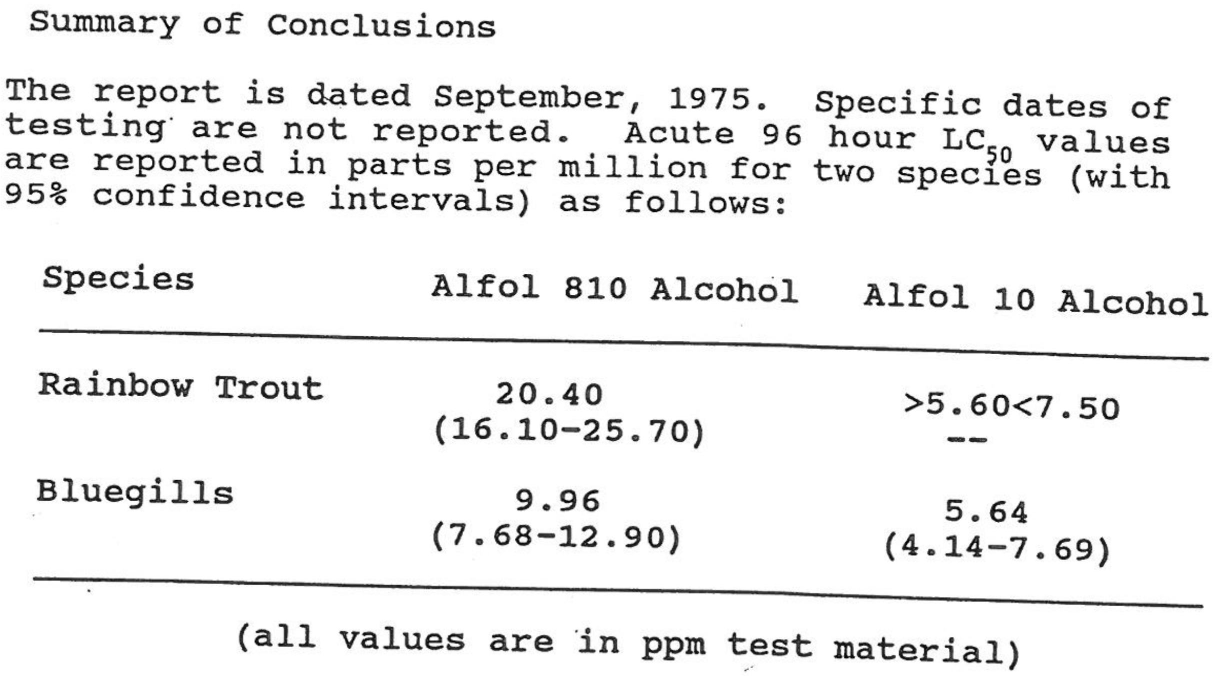
The test material was received on August 14, 1975. The report is dated September 17, 1975. The exact dates of testing are not reported. The acute LC_{50} of Alfol 10 was determined to be in excess of 10,000 ppm in bob-white quail.



Summary of Conclusions

The test material was received on August 14, 1975. The report is dated September 17, 1975. The exact dates of testing are not reported. The acute LC_{50} of Alfol 810 was determined to be in excess of 10,000 ppm in mallard ducks.

Fish Toxicity



Summary of Conclusions

The report is dated September, 1975. Specific dates of testing are not reported. Acute 96 hour LC_{50} values are reported in parts per million for two species (with 95% confidence intervals) as follows:

Species	Alfol 810 Alcohol	Alfol 10 Alcohol
Rainbow Trout	20.40 (16.10-25.70)	>5.60<7.50 --
Bluegills	9.96 (7.68-12.90)	5.64 (4.14-7.69)

(all values are in ppm test material)

Acute Toxicity to Aquatic invertebrates:

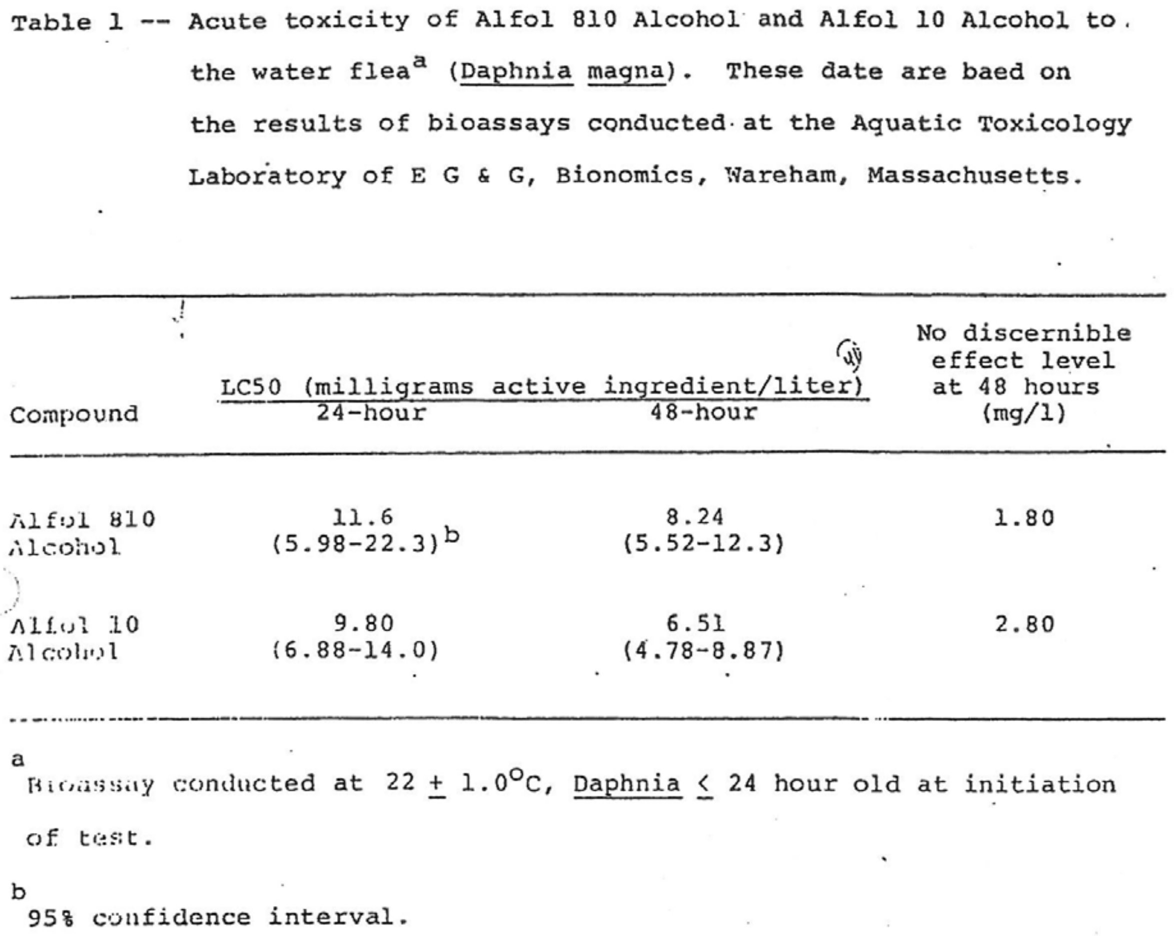


Table 1 -- Acute toxicity of Alfol 810 Alcohol and Alfol 10 Alcohol to the water flea[a] (*Daphnia magna*). These date are baed on the results of bioassays conducted at the Aquatic Toxicology Laboratory of E G & G, Bionomics, Wareham, Massachusetts.

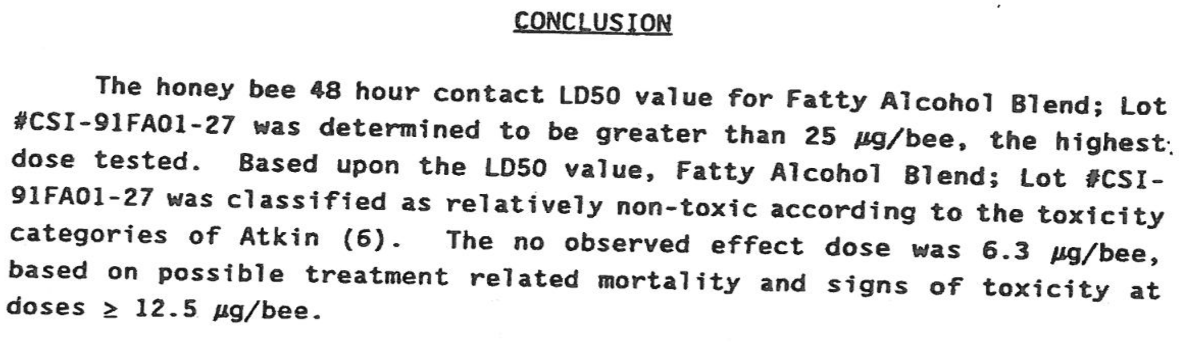
Compound	LC50 (milligrams active ingredient/liter) 24-hour	LC50 (milligrams active ingredient/liter) 48-hour	No discernible effect level at 48 hours (mg/l)
Alfol 810 Alcohol	11.6 (5.98-22.3)[b]	8.24 (5.52-12.3)	1.80
Alfol 10 Alcohol	9.80 (6.88-14.0)	6.51 (4.78-8.87)	2.80

[a] Bioassay conducted at $22 \pm 1.0^{\circ}C$, *Daphnia* $\leq$ 24 hour old at initiation of test.

[b] 95% confidence interval.

Effects on Bees:

1. Active Substance:



CONCLUSION

The honey bee 48 hour contact LD50 value for Fatty Alcohol Blend; Lot #CSI-91FA01-27 was determined to be greater than 25 µg/bee, the highest dose tested. Based upon the LD50 value, Fatty Alcohol Blend; Lot #CSI-91FA01-27 was classified as relatively non-toxic according to the toxicity categories of Atkin (6). The no observed effect dose was 6.3 µg/bee, based on possible treatment related mortality and signs of toxicity at doses ≥ 12.5 µg/bee.

REFERENCES

ECOTOXICOLOGICAL STUDIES:

Author(s)	EPA Guideline Number	Year	Title	Data Protection Claimed	Owner	MRID#
McGaughey, B.	850.2100	1990	Fatty Alcohol Task Force Phase 3 Summary of MRID 00046991. Acute Oral LD_{50} – Mallard Duck: Alfol 810 Alcohol: VISDUCK2: Prepared by Truslow Farms, Inc. 11 p.	Y	Fatty Alcohol Task Force	94313004
McGaughey, B.	850.2200	1990	Fatty Alcohol Task Force Phase 3 Summary of MRID 00058024 Eight Day Dietary LC_{50} Bobwhite Quail: Alfol 810 Alcohol: VISQUL2: Prepared by Truslow Farms, Inc. 10 p.	Y	Fatty Alcohol Task Force	94313006
McGaughey, B.	850.2200	1990	Fatty Alcohol Task Force Phase 3 Summary of MRID 00058025. Eight Day Dietary LC_{50} – Mallard Duck: Alfol 810 Alcohol: VISLCDK2: Prepared by Truslow Farms, Inc. 10 p.	Y	Fatty Alcohol Task Force	94313010
McGaughey, B.	850.1075	1990	Fatty Alcohol Task Force Phase 3 Summary of MRID 00122381. Acute Toxicity of Two Conoco Compounds to Bluegill and Rainbow Trout: VISFISH. Prepared by Bionomics, Inc. 15 p.	Y	Fatty Alcohol Task Force	94313012
LeBlanc G. A.	850.1010	1976	Study of the Effects of Fatty Alcohols on Acute LC50 Freshwater Invertebrates (Daphnia); Report Number: CSI-FATF-TX-9301; EG & Bionomics Aquatic Toxicity Laboratory 13 p.	Y	Fatty Alcohol Task Force	42847201
Hoxter, J. A. and Jaber, M.	850.3020	1992	Fatty Alcohol Blend; Lot # CSI-91FA01-27: An Acute Contact Toxicity Study with the Honey Bee; Project Number. 346-101A: Wildlife International Ltd. 44 p.	Y	Fatty Alcohol Task Force	42495102

d. Effects on human health

1. Active Substance:

Short Term Summary of Mammalian Toxicity:

SPECIES	TEST & EPA Guideline Number	DURATION AND CONDITIONS OR GUIDE LINE ADOPTED	TEST MATERIAL	RESULT	MRID#
Rat	Acute Oral 870.1100	Single Dose Via Oral Route; Observed for 14 Days	Alfol 810 DF Lot# 1169975	>5000 mg/kg	47589902
Rat	Acute Dermal 870.1200	Single Dose; 24 hour Exposure; observed for 14 Days	Alfol 810 DF Lot# 1169975	>5000 mg/kg	47589903
Rabbits	Primary Eye Irritation 870.2400	Observations Post Instillation at 1 HR, 24 HRS, 48 HRS, 72 HRS, 4 Days, 7 Days	Alfol 810 DF Lot# 1169975	Moderately Irritating	47589904
Rabbits	Primary Skin Irritation 870.2500	Single Topical Exposure for 4 Hours with Evaluations Made After patch Removal at 30 -60 Minutes, 24 HRS, 48 HRS, 72 HRS, 7 days	Alfol 810 DF Lot# 1169975	Moderately Irritating	47589905
Rats	Acute Inhalation 870.1300	Single Nose-Only Exposure for 4 Hours	Alfol 810 DF Lot# 1169975	LC_{50}>2.07 mg/L	47777501
Guinea Pigs	Skin Sensitization 870.2600	Buehler Test For Sensitization	Fatty Alcohol Blend, Batch No. CSI-91FAO1-27	Not a Sensitizer	43380201

Summary of Mammalian Toxicity (CONT):

SPECIES	TEST & EPA GUIDELINE NUMBER	DURATION AND CONDITIONS OR GUIDE LINE ADOPTED	TEST MATERIAL	RESULT	MRID#
Salmonela Typhimurium Strains: TA 1535 TA 1537, TA 1538, TA 98 and TA100	Mutagenicity 870.5140		Fatty Alcohol Blend, Batch No. CSI-91FAO1-27	No Mutagenic Activity in any of the 5 Bacterial Strains Used	42372002
Mice	Micronucleus Test in Bone Marrow 870.8380		Fatty Alcohol Blend, Batch No. CSI-91FAO1-27	Maximum Tolerated Dose in the Toxicity Study >2000 mg/kg/day No Evidence of Micronucleus Induction was Detected in Bone Marrow Erythrocytes	42372001
Mice	Mouse Lymphoma L5178Y Mutation Assay 870.5100		Fatty Alcohol Blend, Batch No. CSI-91FAO1-27	No Evidence of Mutagenic Activity in any of the 4 assays Evaluated	42372003
Sprague-Dawley Rats	Teratogenicity Using Dose Levels of 0,125,375,1000 mg/kg/day 870.3700		Fatty Alcohol Blend, Batch No. CSI-91FAO1-27	No Notable Effects on the Dam or the Conceptus at Dose Levels of up to 1000 mg/kg/day	42609301

REFERENCES

TOXICOLOGICAL AND METABOLISM STUDIES

Author(s)	**EPA Guideline Number**	**Year**	**Title**	**Data Protection Claimed**	**Owner**	**MRID#**
Moore, G. E.	870.1100	10/2008	Alfol 810 DF: Acute Oral Toxicity Up and Down Procedure in Rats: Laboratory Study Number: 25549: Eurofins/ Product Safety Laboratories: 10/14/2008; 16 p.	Y	Fatty Alcohol Task Force	47589902
Moore, G. E.	870.1200	10/2008	Alfol 810 DF: Acute Dermal Toxicity Study procedure in Rats: Laboratory Study Number: 25541: Eurofins/ Product Safety Laboratories: 10/14/2008; 15 p.	**Y**	**Fatty Alcohol Task Force**	**47589903**
Moore, G. E.	870.2400	10/2008	Alfol 810 DF: Primary Eye Irritation Study in Rabbits; Eurofin/ Product Safety Laboratories, Laboratory Study Number: 25543; 10/14/2008 18 p.	Y	Fatty Alcohol Task Force	47589904
Moore, G. E.	870.2500	10/2008	Alfol 810 DF: Primary Skin Irritation Study in Rabbits; Laboratory Study Number: 25544 Eurofins/Product Safety Laboratories; 10/14/2008, 16 p.	Y	Fatty Alcohol Task Force	47589905

TOXICOLOGICAL AND METABOLISM STUDIES

Author(s)	**EPA Guideline Number**	**Year**	**Title**	**Data Protection Claimed**	**Owner**	**MRID#**
Wilson, J.		1991	Fatty Alcohol Blend (FAB): Dose Range finding Study in Rats: Lab Study Number: 490311: 7768. Unpublished study prepared by Inveresk Research International. 42 p.	Y	Fatty Alcohol Task Force	42634201
Jackson, D.; Wilson, J.	870.2600	1994	Fatty Alcohol Blend C_6-C_{12}: Buehler Skin Sensitization Test in Guinea Pigs: Lab Project Number: 555677: 10500: 94014 / FATF. Unpublished study prepared by Inveresk Research International. 65p.	Y	Fatty Alcohol Task Force	43386201
Naas, D.	870.3250	1994	A 90-Day Dermal Toxicity Study of Fatty Alcohol Blend in rats: Final Report: Lab Project Number: WIL-241001: 94013-FATF. Unpublished Study prepared by WIL Research Labs, Inc. 486 p.	Y	Fatty Alcohol Task Force	43701201
Durando, J.	870.1300	5/2009	Alfol 810 DF; Acute Inhalation Toxicity Study in Rats-Limit Test; Lab Study Number 26969; Eurofins/ Product Safety Laboratories, 5/5/09, 23 p.	Y	Fatty Alcohol Task Force	47777501

TOXICOLOGICAL AND METABOLISM STUDIES

Author(s)	**EPA Guideline Number**	**Year**	**Title**	**Data Protection Claimed**	**Owner**	**MRID#**
Holstrom, M.; Innes, D.	870.8380	1992	Fatty alcohol Blend Micronucleus test in Bone Marrow of CD-1 Mice: Lab Project Number: 8568: 751943. Unpublished study prepared by Inveresk Research International. 39 p.	Y	Fatty Alcohol Task Force	42372001
Dillon, D.; McCartney, M.	870.5140	1992	Fatty Alcohol Blend Lot No. CSI-91FA01-27" Testing for Mutagenic Activity with Salmonella typhimurium TA 1537, TA 1538, TA 98 and TA 100: Lab Project Number: 751938; 8604. Unpublished study prepared by Inveresk Research International. 49 p.	Y	Fatty Alcohol Task Force	42372002
Cattananch, P.; Riach, C.	870.5100	1992	Fatty Alcohol Blend Mouse Lymphoma Mutation Assay: Lab Project Number: 751985: 8715. Unpublished study prepared by Inveresk Research International. 55 p.	Y	Fatty Alcohol Task Force	42372003

TOXICOLOGICAL AND METABOLISM STUDIES

Author(s)	EPA Guideline Number	Year	Title	Data Protection Claimed	Owner	MRID#
Wilson, J.; Hazelden, K.	870.3700	1992	Teratogenicity Study in Rats: Fatty Alcohol Blend (FAB): Lab Project Number: 490327: 7821. Unpublished study prepared by Inveresk Research International. 72 p.	**Y**	**Fatty Alcohol Task Force**	**42609301**

2**. Formulated (end use product):**

N-TAC:

Short Term Summary of Mammalian Toxicity:

SPECIES	TEST	EPA Guideline Number	TEST MATERIAL	RESULT	MRID#
Rat	Acute Oral	870.1100	N-TAC	>5000 mg/kg	49218303
Rat	Acute Dermal	870.1200	N-TAC	>2000 mg/kg	49218304
Rat	Acute inhalation	8870.1300	N-TAC	>2.09 mg/l	49218305
Rabbit	Primary Eye Irritation	870.2400	N-TAC	Extremely Irritating	49218306
Rabbit	Primary skin Irritation	870.2500	N-TAC	Slightly irritating	49218307
Mice	Dermal Sensitization	870.2600	N-TAC	Contact dermal sensitizer at concentrations >25%	49218308

References:

Author	EPA GUIDELINE NUMBER	YEAR	TITLE	OWNER	MRID#
Lowe, Carolyn	870.1100	2013	Acute Oral	Fair Products, Inc.	49218303
Lowe, Carolyn	870.1200	2013	Acute Dermal	Fair Products, Inc.	49218304
Lowe, Carolyn	8870.1300	2013	Acute inhalation	Fair Products, Inc.	49218305
Lowe, Carolyn	870.2400	2013	Primary Eye Irritation	Fair Products, Inc.	49218306
Lowe, Carolyn	870.2500	2013	Primary skin Irritation	Fair Products, Inc.	49218307
Lowe, Carolyn	870.2600	2013	Dermal Sensitization	Fair Products, Inc.	49218308

Titles

1. N-TAC: Acute Oral Toxicity Up and Down Procedure in Rats – Limit Test; Product Safety Labs, Laboratory Study Number 36692; August 20, 2013; 14 pp.

2. N-TAC: Acute Dermal Toxicity Study in Rats- Limit Test; Product Safety Labs; Laboratory Study Number 36693, August 20, 2013; 14pp.

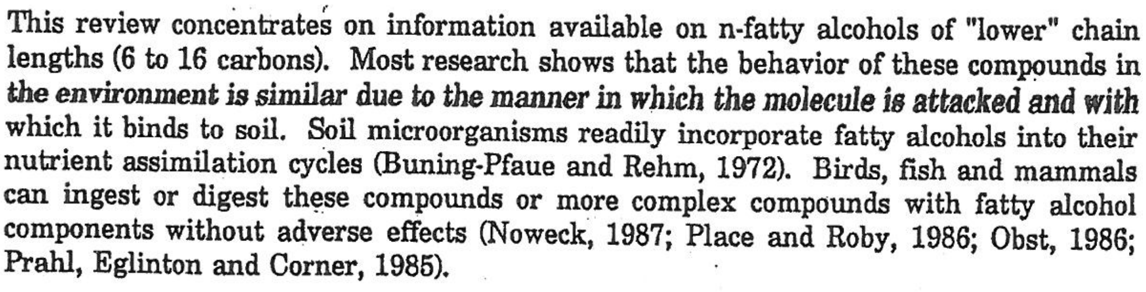
3. N-TAC: Acute Inhalation Toxicity Study in Rats- Limit Test; Product Safety Labs; Laboratory Study Number 36694; August 20, 2013; 21pp.

4. N-TAC: Primary Eye Irritation Study in Rabbit; Product Safety Labs; Laboratory Study Number 36695, August 20, 2013; 17pp.

5. N-TAC: Primary Skin Irritation Study in Rabbit; Product Safety Labs; Laboratory Study Number 36696; August 21, 2013; 14 pp.

6. N-TAC: Local Lymph Node Assay (LLNA) in Mice; Product Safety Labs; Laboratory Study number 36697; August 20, 2013; 24pp.

e. **Effects on soil organisms, crops, or livestock:**



This review concentrates on information available on n-fatty alcohols of "lower" chain lengths (6 to 16 carbons). Most research shows that the behavior of these compounds in the environment is similar due to the manner in which the molecule is attacked and with which it binds to soil. Soil microorganisms readily incorporate fatty alcohols into their nutrient assimilation cycles (Buning-Pfaue and Rehm, 1972). Birds, fish and mammals can ingest or digest these compounds or more complex compounds with fatty alcohol components without adverse effects (Noweck, 1987; Place and Roby, 1986; Obst, 1986; Prahl, Eglinton and Corner, 1985).

Effects on Terrestrial Vascular Plants (corn, onion, sorghum, wheat, carrot, cucumber, lettuce, radish, soybean and tomato).

Effects on Terrestrial Vascular Plants:

There were no phytotoxic abnormalties observed in any of the species from any of the treatments. Overall, emergence was excellent, however, onions and carrots were much slower emerging than the other species (non-treated controls included) . This resulted in no emergence data collected at 7 days after treatment for these species . This effect was not treatment related. There was no detrimental effects from the fatty alcohol on seedling emergence or total fresh weight. Height of tomatoes and radishes, at 21 DAT, was reduced in the fatty alcohol treatment by 11 and 15%,
respectively.

CONCLUSIONS

These data indicate that the fatty alcohol blend rate necessary to cause economically adverse effects on these species is greater than the maximum labeled use rate. These data coupled with the fact that the fatty alcohol blend is commercially applied to tobacco in a manner
which significantly reduces the likelihood of off- target movement indicates that this product poses little threat (to non-target plant species. These data indicate that a more elaborate multiple rate study (Tier 2) is not necessary to assess the potential impact of continued use of fatty alcohol blends in commercial tobacco production.

References

Author(s)	EPA Guideline Number	Year	Title	Data Protection Claimed	Owner	MRID#
Willard, T.	850.4200	1992	Study of the Effects of Fatty Alcohol Blend on Seed Germination and Seedling Emergence: A Tier I Terrestrial Non-Target Plant Hazard Evaluation: Lab Project Number. CSI-FATF-SFEI-92: FATF-9202: Unpublished study prepared by American Agricultural Services 142 p.	Y	Fatty Alcohol Task Force	42495101
Massey, L.	850.4200	1993	Study of the Effects of Fatty Alcohol Blend on Seed Germination and Seedling Emergence: A Tier I Terrestrial Non-Target Plant Hazard Evaluation: Amendment to MRID 42495101: Lab Project Number. CSI-FATF-SGEI-92: FATF-9202: Unpublished Study prepared by American Agricultural Services 6 p.	Y	Fatty Alcohol Task Force	42631901
Willard, T.	850.4150	1992	Study of the Effects of Fatty Alcohol Blend on Plant Vegetative Vigor: A Tier 2 Terrestrial Non-Target Plant Hazard Evaluation: Lab Project Number. FATF-9203: CSI-FATF-VV2-92: Unpublished study prepared by American Agricultural Services 126 p.	Y	Fatty Alcohol Task Force	42514701
Massey, L	850.4150	1993	Study of the Effects of Fatty Alcohol Blend on Plant Vegetative Vigor: A Tier 2 Terrestrial Non-Target Plant Hazard Evaluation: Amendment to MRID 42514701: Lab project number: CSI-FATF-VV2-92: FATF-9203. Unpublished study prepared by American Agricultural Services, Inc. 7 p.	Y	Fatty Alcohol Task Force	42631902

ITEM B.11 Safety Information

INCLUDED HERE ARE THE FOLLOWING SAFETY DATA SHEETS:

Active Ingredients C_6, C_8, C_{10}, C_{12} - **Naturally Derived Fatty Alcohol**

Trade Name for this ingredient is **MASCOL 80**

FORMULATED PRODUCT:

O-TAC PLANT CONTACT AGENT

N-TAC (As Plant Contact Agent)

INERT INGREDIENTS:

CRODA TWEEN 80

PT. MUSIM MAS

Fatty Alcohol, Methyl Esters and Derivatives

SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Product Identification

Product Name : Octyl Decyl Alcohol
Trade Name : MASCOL 80
Other Identifier : Alcohols C6-C12, 1-Octanol+1-Decanol.
Recommended Use : Cosmetic base product for industrial purpose. General chemicals, as they are used in many ways in the chemicals industry.

Company Identification

Manufacturer Name : PT Musim Mas
Address : Jl. Oleo, Kawasan Industri Medan II,
Saentis - Percut Sei Tuan, Deli Serdang
Medan 20371 - Indonesia
Telephone Number : 62-61-6871123
Fax Number : 62-61-6871152 / 6871153
Email Address : *oleo@musimmas.com*
Emergency Telephone Number : +62-8116054139

2. HAZARD IDENTIFICATION

GHS Classification
- Physical Hazard : Not classified as hazardous substance
- Health Hazard : Serious eye damage / eye irritation, Category 2
- Environmental Hazard : Not classified as hazardous substance

GHS Label Element
- Hazard Symbol :
- Signal Word : Warning
- Hazard Statement : H319 Causes Serious eye irritation
- Precautionary Statement : P264 Wash hands thoroughly after handling.
  P280 Wear protective gloves/protective clothing/eye protection
  P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  P337+P313 If eye irritation persists: Get medical advice/attention.

Other Hazard : No information available

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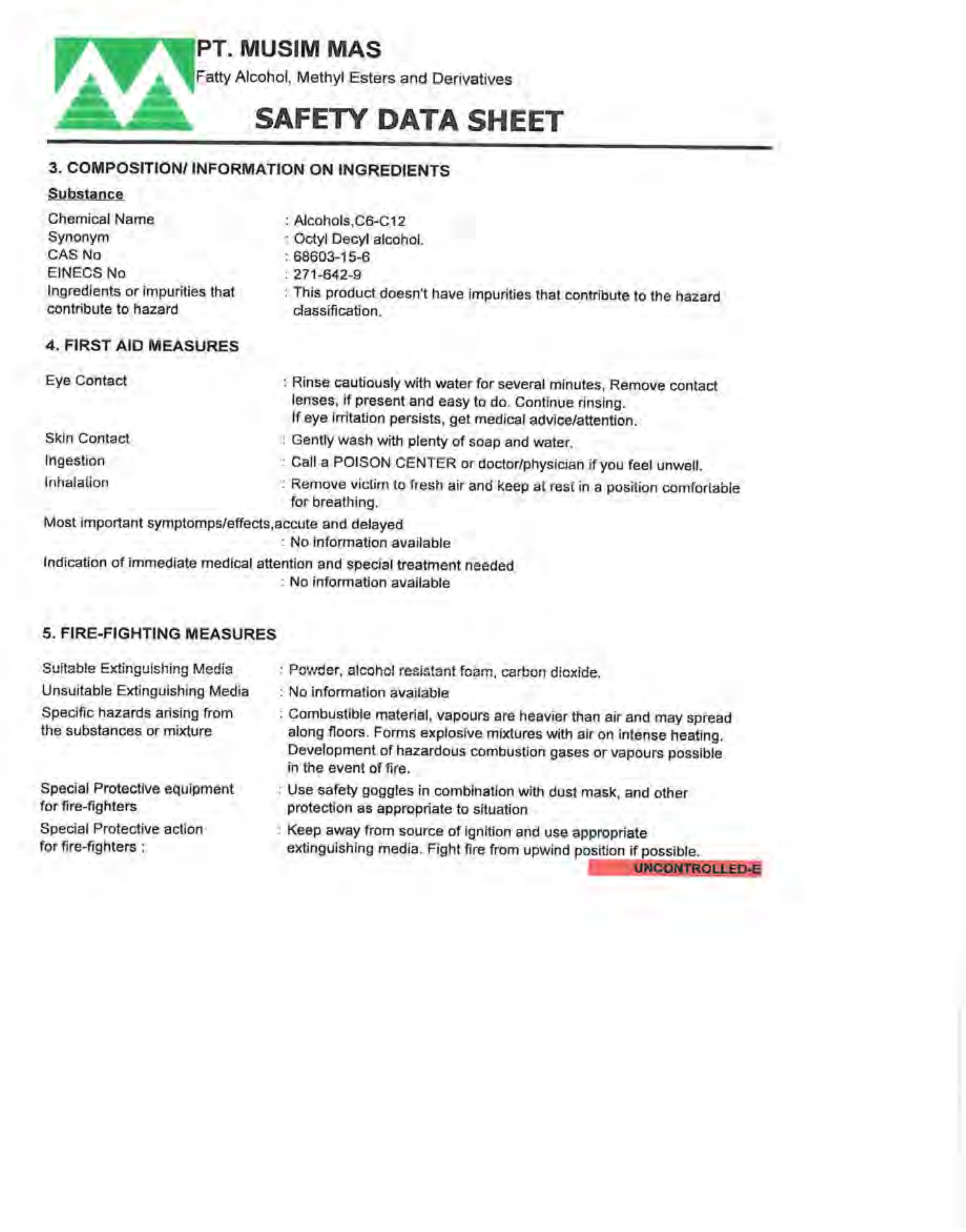

PT. MUSIM MAS

Fatty Alcohol, Methyl Esters and Derivatives

SAFETY DATA SHEET

3. COMPOSITION/ INFORMATION ON INGREDIENTS

Substance

Chemical Name	: Alcohols,C6-C12
Synonym	: Octyl Decyl alcohol.
CAS No	: 68603-15-6
EINECS No	: 271-642-9
Ingredients or impurities that contribute to hazard	: This product doesn't have impurities that contribute to the hazard classification.

4. FIRST AID MEASURES

Eye Contact	: Rinse cautiously with water for several minutes, Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.
Skin Contact	: Gently wash with plenty of soap and water.
Ingestion	: Call a POISON CENTER or doctor/physician if you feel unwell.
Inhalation	: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

Most important symptomps/effects,accute and delayed
: No information available

Indication of immediate medical attention and special treatment needed
: No information available

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media	: Powder, alcohol resistant foam, carbon dioxide.
Unsuitable Extinguishing Media	: No information available
Specific hazards arising from the substances or mixture	: Combustible material, vapours are heavier than air and may spread along floors. Forms explosive mixtures with air on intense heating. Development of hazardous combustion gases or vapours possible in the event of fire.
Special Protective equipment for fire-fighters	: Use safety goggles in combination with dust mask, and other protection as appropriate to situation
Special Protective action for fire-fighters :	: Keep away from source of ignition and use appropriate extinguishing media. Fight fire from upwind position if possible.

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PT. MUSIM MAS
Fatty Alcohol, Methyl Esters and Derivatives

SAFETY DATA SHEET

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use safety goggles and protective gloves.
Large spills : Remove person to safety. Ensure adequate ventilation.

Environmental precautions : Avoid release to the environment.

Methods and materials for containment and cleaning up : Small spills : Absorb spills with sand, inert absorbent, waste cloth or sawdust. Then wipe up remainder in waste cloth.
Large spills : Dike spills and dispose of in safe area.

7. HANDLING AND STORAGE

Precautions for safe Handling : Use an adequate ventilation.
Wash thoroughly after handling.
Used personal protective equipment as required.

Conditions for safe storage including any incompatibilities : Store container tightly closed in well-ventilate place.
Do not store together with oxidizing agents.
Keep away from source of ignitions.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Appropriate Engineering Controls : Facilities storing or utilizing this materials should be equipped with an eyewash facilities and safety shower

Individual Protection Measures, such as personal protective equipment
Eye/Face Protection : Tightly seal safety glasses.
Skin Protection : Wear suitable protective clothing and glove (butyl rubber, nitrile rubber).
Respiratory Protection : If technical suction or ventilation measures are not possible or are insufficient, protective breathing apparatus must be worn.
Thermal Hazards : Not applicable
Environmental Exposure Controls : Do not empty into drains.

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PT. MUSIM MAS
Fatty Alcohol, Methyl Esters and Derivatives

SAFETY DATA SHEET

9. PHYSICAL AND CHEMICAL PROPERTIES

Basic Information	
Appearance	
Physical State	: Liquid
Colour	: Colourless
Odour	: Fishy alcohol
Odour threshold	: No information available
pH	: No information available
Melting Point/freezing point	: -11°C
Initial Boiling point and boiling range	: 204 - 238°C @ 1 atm
Flash point	: 96°C PMCC
Evaporation Rate	: No information available
Flammability (solid,gas)	: No information available
Upper/lower flammability or explosive limits	: No information available
Vapour pressure	: 0.058mmHg (7.7 Pa) at 24°C
Vapour density	: No information available
Relative density	: 0.818 g/cm^3 @ 30°C
Solubility	: Water solubility : < 500 mg/L at 25°C Solvent solubility : Soluble in general organic solvent
Partition coefficient :n-octanol/water	: log Pow : 3.5 - 4.7
Auto-ignition temperature	: Approx 260°C
Decomposition temperature	: No information available
Viscosity	: 8 mPa.s (30°C)
Explosive properties	: No information available
Oxidizing properties	: No information available
Other Information	: No information available

10. STABILITY AND REACTIVITY

Reactivity	: Stable in general
Chemical stability	: Stable in general
Possibility of hazardous reactions	: No information available
Conditions to avoid	: Do not expose to extreme heat or flame
Incompatible materials	: Strong oxidizing agents
Hazardous decomposition products	: Carbon Monoxide Complete combustion forms carbon dioxide and water. Partial combustion also forms carbon monoxide, soot, aldehydes and ketones

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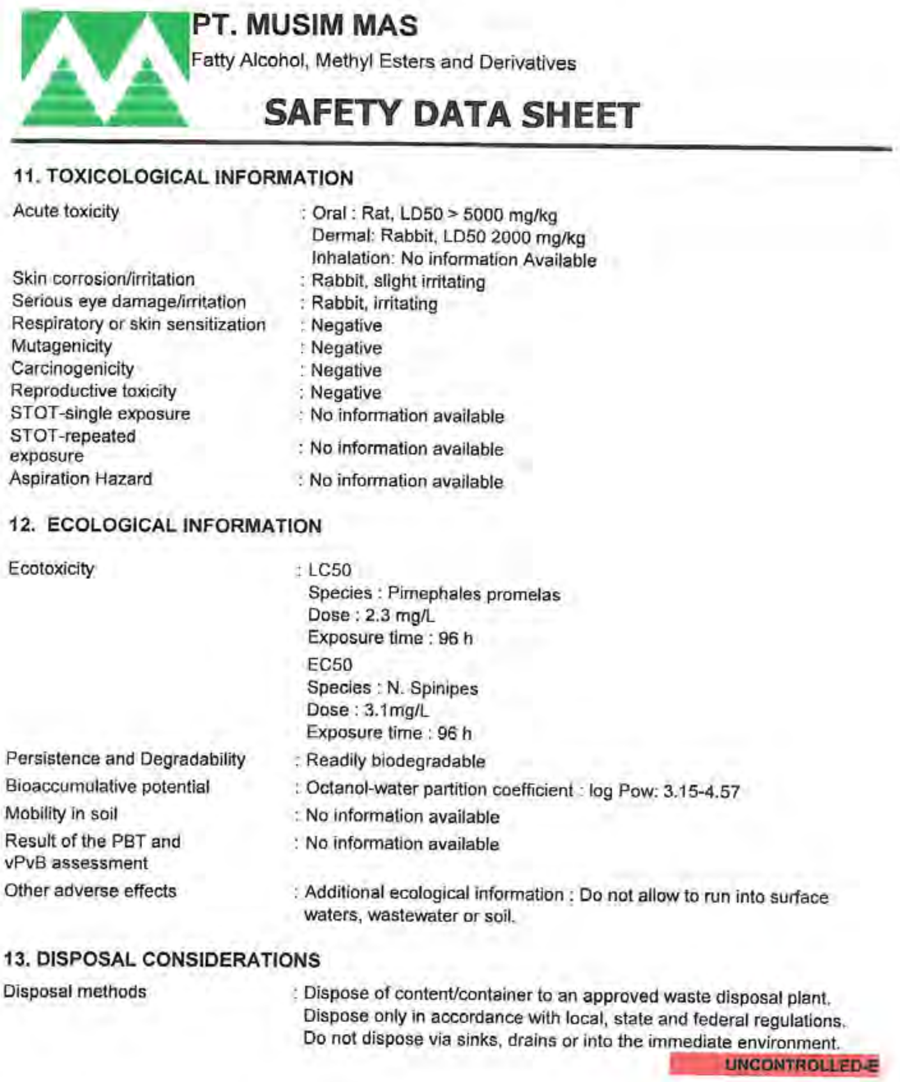

PT. MUSIM MAS

Fatty Alcohol, Methyl Esters and Derivatives

SAFETY DATA SHEET

11. TOXICOLOGICAL INFORMATION

Acute toxicity	: Oral : Rat, LD50 > 5000 mg/kg Dermal: Rabbit, LD50 2000 mg/kg Inhalation: No information Available
Skin corrosion/irritation	: Rabbit, slight irritating
Serious eye damage/irritation	: Rabbit, irritating
Respiratory or skin sensitization	: Negative
Mutagenicity	: Negative
Carcinogenicity	: Negative
Reproductive toxicity	: Negative
STOT-single exposure	: No information available
STOT-repeated exposure	: No information available
Aspiration Hazard	: No information available

12. ECOLOGICAL INFORMATION

Ecotoxicity	: LC50 Species : Pimephales promelas Dose : 2.3 mg/L Exposure time : 96 h EC50 Species : N. Spinipes Dose : 3.1mg/L Exposure time : 96 h
Persistence and Degradability	: Readily biodegradable
Bioaccumulative potential	: Octanol-water partition coefficient : log Pow: 3.15-4.57
Mobility in soil	: No information available
Result of the PBT and vPvB assessment	: No information available
Other adverse effects	: Additional ecological information : Do not allow to run into surface waters, wastewater or soil.

13. DISPOSAL CONSIDERATIONS

Disposal methods	: Dispose of content/container to an approved waste disposal plant. Dispose only in accordance with local, state and federal regulations. Do not dispose via sinks, drains or into the immediate environment.

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14. TRANSPORT INFORMATION

Land Transport (US-DOT) : Not classified
Land Transport (ADR/RID) : Not classified
Sea Transport (IMDG Code) : Not classified
Air Transport (IATA) : Not classified
Inland waterways Transport (ADN) : Not classified
Transport in Bulk (Annex II of MARPOL 73/78 and the IBC code)
Product Name : Alcohols(C8-C11), primary, linear and essential linear.
Ship Type : 2
Pollution category : Y

15. Regulatory Information

Inventories List
AICS (Australia) : Listed
DSL (Canada) : Listed
NDSL (Canada) : No
IECSC (China) : Listed
EINECS (EU) : 271-642-9
ENCS (Japan) : Listed
ECL (Korea) : Listed
NZIoC (New Zealand) : Listed
PICCS (Philippines) : Listed
TSCA (USA) : Listed

Chemical Safety assessment : No information available.

16. OTHER INFORMATION

Document No. : SDS-FAQ-11
Revision No. : 2.00
Issue date : 18-Jul-14

Disclaimer

Safety Data Sheet

fair products, inc.

O-TAC PLANT CONTACT AGENT

Version: 2.0 Revision Date: 12/15/2015 Print Date: 12/15/2015

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

a) Product Name:	O-TAC PLANT CONTACT AGENT
b) Chemical Name:	Fatty Alcohol Blend (n-octanol, n-decanol)
c) Product Use Description:	Plant Growth Regulator
EPA Registration Number	51873-18
d) Company:	Fair Products, Inc. P.O. Box 386 Cary, NC 27512 United States of America Telephone: (US) 919-467-1599
e) Emergency Telephone:	Chemtrec: (24 hours) 800-424-9300
Prepared by:	Fair Products, Inc.

SECTION 2. HAZARDS IDENTIFICATION

a) Classification of the substance

GHS CLASSIFICATION IN ACCORDANCE WITH 29CFR1910 (OSHA HCS)

Irritating to skin (category 2), H315
May cause allergic skin reaction (category 1) H317
Causes serious damage to eyes (category 2A), H318
Specific target organ toxicity –single exposure (category 3), Respiratory system, H335
Aquatic acute toxicity (category 2), H401
For the full text of the H-Statements mentioned in this section, see Section 16

GHS LABEL ELEMENTS:

SIGNAL WORD: DANGER

HAZARD STATEMENTS

H315	causes skin irritation
H317	may cause allergic skin reaction
H318	causes serious damage to eyes
H335	may cause respiratory irritation
H401	toxic to aquatic life

PRECAUTIONARY STATEMENTS

P264	Wash skin thoroughly after handling.
P273	Avoid release into environment.
P280	Wear protective gloves/eye protection/face protection.
P302 & P352	IF ON SKIN: Wash with plenty of soap and water.
P305 & P351 & P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 & P313	If exposed or concerned: Get medical advice/attention.
P321	Specific treatment (see supplemental first aid instructions on this label).
P332 & P313	If skin irritation occurs: Get medical advice/attention.
P337 & P313	If eye irritation persists: Get medical advice/attention.
P362	Take off contaminated clothing and wash before reuse.
P403 & P233 P235	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up. Keep cool.
P501	Dispose of contents/container to an approved waste disposal plant.

Hazards not otherwise classified (HNOC) or not covered by GHS – None

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name:	n-decanol n-octanol
Common Name:	Fatty Alcohol Blend
Synonyms:	NONE
CAS-NO:	112-30-1 (n-decanol) 111-87-5 (n-octanol)

Weight Percent:	
n-decanol:	48.2%
n-octanol:	36.2%
Polyoxyethylene sorbitan monooleate/9005-65-6:	15.3%
Related compounds (dodecanol C-12) 112-53-8:	0.3%

SECTION 4. FIRST AID MEASURES

First aid procedures

Inhalation	If breathed in, move person to fresh air. If breathing has stopped artificial respiration should be started. Seek medical attention if symptoms develop.
Skin contact	Remove contaminated clothing. Wash thoroughly with soap and warm water. If irritation persists, seek medical advice/attention. Wash contaminated clothing before re-use.
Eye contact	Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Seek medical attention if irritation persists.
Ingestion	Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. DO NOT induce vomiting unless told to do so by a Poison Control Center or doctor. Never give anything by mouth to an unconscious or convulsing person.

SECTION 5. FIREFIGHTING MEASURES

Flammable properties

Flash point: > 200°F

Firefighting

Suitable extinguishing media: Water spray, carbon dioxide (CO_2), dry chemical or foam.

Unsuitable extinguishing media: Do not use water jet, as this may spread burning material.

Firefighting procedures: Protect against inhalation of combustion products. Assure self-contained breathing apparatus is worn. Prevent runoff if possible.

Further information: Fight fires from a safe distance. Move containers from fire area if possible. Use water spray to cool unopened containers.

Protective equipment and precautions for firefighters: Wear body covering protective clothing and self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Ensure adequate ventilation. Wear suitable protective clothing, chemical resistant gloves, goggles, safety glasses or face shield. Avoid contact with skin and eyes.

Environmental precautions: Prevent from entering sewer system, surface water or soil.

Methods for containment: Absorb on an inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).

Methods for cleaning up: Avoid dispersion of dust. Sweep up and collect in a suitable container for disposal.

Further information: Keep in properly labeled containers.

Disposal: Dispose of in accordance with Local, State and Federal Regulations.

SECTION 7. HANDING AND STORAGE

Handling Procedures:	Wear suitable protective clothing, gloves and eye/face protection. Avoid inhalation, ingestion and contact with skin and eyes. Handle and open container with care. Protect from contamination. Use only in well-ventilated areas. Wash thoroughly after handling. Keep container closed when not in use.
Requirements for Storage:	Store original containers away from direct heat, store in a cool, dry and well-ventilated area away from food, water and feed. Keep container tightly closed and maintain only in the original container.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines	Contains no substance with occupational exposure limit values.
Personal protective equipment	
Eye protection:	Protective eyewear, such as goggles, safety glasses or face shield.
Hand protection:	Chemical resistant protective gloves.
Skin and body protection:	Long-sleeve shirt and long pants or coveralls. Rubber or plastic boots. Remove and wash contaminated clothing before re-use.
Respiratory protection:	Wear a dust respirator if dusting conditions exist.
Hygiene measures:	Observe good personal hygiene and safety practices. Avoid contact with skin, eyes or clothing. Wear chemical resistant gloves and eye/face protection. Do not inhale aerosol. Avoid prolonged inhalation of mists. Ensure adequate ventilation especially in confined areas. Do not eat, drink or smoke when using. Wash hands thoroughly after handling. Remove and wash contaminated clothing before re-use.
Engineering Controls	
Ventilation:	General mechanical room ventilation is satisfactory for normal handling and storage operations.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

a) Appearance	
Form:	liquid
Color:	yellow
b) Odor:	characteristic alcohol odor
c) Odor Threshold:	No data available
d) pH:	7 - 8
e) Melting point/freezing point:	No data available
f) Initial boiling point and boiling range:	204 -238°C – (Technical)
g) Flash point:	>200°F
h) Evaporation rate:	No data available
I) Flammability (solid, gas):	Not applicable
j) Upper/lower flammability or explosive limits:	approximately 5.3% (v) / approximately 0.8% (v)- (Technical)
k) Vapor pressure:	0.66 mm Hg @ 24°C (Technical)
l) Vapor density:	4.5 – 5.5 (Technical)
m) Relative density:	0.85 gms/cc
n) Water solubility:	0.0035 g/ml @ 25°C (Technical)
o) Partition coefficient:	n-octanol/water: log POW: 2.3 – 4.2
p) Auto-ignition temperature:	260°C (Technical)
q) Decomposition temperature:	No data available
r) Viscosity:	14.9 CPS@ 25°C

SECTION 10. STABILITY AND REACTIVITY

a) Reactivity:	No data available
b) Chemical stability:	Stable at ambient temperatures and pressures.
c) Possibility of hazardous reactions:	Hazardous polymerization will not occur.
d) Conditions to avoid:	Excessive heat.
e) Incompatible materials:	Strong acids and bases; strong oxidizing agents.
f) Hazardous decomposition products:	Oxides of carbon and nitrogen.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute Oral Toxicity:	LD_{50} >5000 mg/kg (Rat)
Acute Dermal Toxicity:	LD_{50} >2000 mg/kg/bw (Rat)
Acute Inhalation Toxicity:	LC_{50} >2.09 mg/l (Rat)
Primary Skin Irritation:	Slightly irritating (Rabbit)
Primary Eye Irritation:	Extreme irritation (Rabbit)
Skin Sensitization:	Considered a contact dermal sensitizer at concentration of 25% and above (LLNA in mice). Not a sensitizer (Guinea Pig)

Carcinogenicity:

IARC	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
OSHA	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
NTP	No component of this product present at levels greater than or equal to 0.1% is identified as known or anticipated carcinogen by NTP.
ACGIH	No component of this product present at levels greater than or equal to 0.1% is identified as a potential carcinogen by ACGIH.

Toxicological Assessment

CMR Effects:	Carcinogenicity:	negative
	Mutagenicity:	negative
	Reproductive Toxicity:	negative

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity Effects

Toxicity to fish:	96 hours LC_{50} Rainbow trout: 20.4 ppm 96 hours LC_{50} Bluegill: 9.96 ppm
Toxicity to Daphnia and other aquatic invertebrates:	48 hour LC_{50} to Daphnia magna (water flea): 8.24 mg/l
Toxicity to birds:	Acute oral LD_{50} to Mallard Ducks: >4640 mg/kg/bw Eight Day Dietary LC_{50} to: Bobwhite Quail - >10,000 ppm Mallard Ducks - >10,000 ppm
Toxicity of honey bees:	48 hour contact LD_{50} >25 µg/bee

Elimination Information (persistence and degradability)

Biodegradability:	Readily biodegradable

SECTION 13. DISPOSAL CONSIDERATION

Further information:

Dispose of waste material in compliance with all federal, state and local regulations.
Avoid discharge to sewers and natural waterways.

Empty drums should be decontaminated and either passed to an approved drum reconditioned or destroyed. Containers that cannot be cleaned must be treated as waste.

SECTION 14. TRANSPORT INFORMATION

a)	UN Number:	Not Regulated
b)	UN Proper shipping name:	Environmentally hazardous substance, liquid, n.o.s.
c)	Transport hazard class:	Not Regulated
d)	Packing group:	Not Regulated
e)	Marine Pollutant:	No
f)	Transport bulk:	Not Regulated
g)	Special precautions:	None

DOT
Not dangerous goods

TDG
Not dangerous goods

IATA
Not dangerous goods

IMDG
Not dangerous goods

RID
Not dangerous goods

SECTION 15: REGULATORY INFORMATION

OSHA Hazards	This material is hazardous under the criteria of the Federal OSHA Hazard Communication standard 29CFR 1910.1200.
SARA 302:	No chemicals in this material are subject to the reporting requirements for SARA Title III, Section 302.
SARA 311/312:	Acute Health Hazard.
SARA 313	This material does not contain any chemical components.
EPA FIFRA Information:	This chemical is a pesticide product registered by the U.S. EPA and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets (SDS), and for workplace labels of non-pesticide chemical. The hazard information required on the pesticide label is listed out below. The pesticide label also includes other important information, including directions for use.

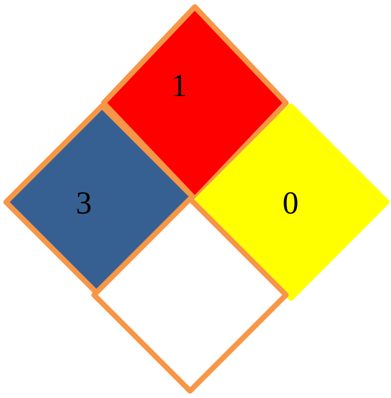
EPA / CERCLA Reportable Quantity:	None known

The components of this product are reported in the following inventories:

REACH	Not in compliance with the inventory.
CH INN	On the inventory, or in compliance with the inventory.
US. TSCA	On TASCA inventory.
DSL	All components of this product are in the Canadian DSL list.
AICS	On inventory or in compliance with the inventory.
NXIOC	On inventory or in compliance with the inventory.
ENCS	On inventory or in compliance with the inventory.
ISHL	On inventory or in compliance with the inventory.
KECI	On inventory or in compliance with the inventory.
PICCS	On inventory or in compliance with the inventory.
IECSC	On inventory or in compliance with the inventory.
TSCA list information:	US Toxic Substance Control Act (TSCA) Section 12 (b) Export Notification (40 CFR 707, Subpt D) ZUS T12B

SECTION 16. OTHER INFORMATION

HMIS Classification:	Health hazard: 3 Flammability: 1 Reactivity: 0
NFPA Classification: Fire hazard: 1	Health hazard: 3 Reactivity hazard: 0



This information in this Material Safety Data Sheet is correct to the best of our knowledge and information at the date of its publication. The information provided is designed only as a guidance document for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification.

Safety Data Sheet

fair products, inc.

N-TAC

Version: 2.0 Revision Date: 12/15/2015 Print Date: 12/15/2015

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

a) Product Name:	N-TAC
b) Chemical Name:	Fatty Alcohol Blend (n-octanol, n-decanol)
c) Product Use Description:	Plant Growth Regulator
EPA Registration Number	51873-20
d) Company:	Fair Products, Inc. P.O. Box 386 Cary, NC 27512 United States of America Telephone: (US) 919-467-1599
e) Emergency Telephone:	Chemtrec: (24 hours) 800-424-9300
Prepared by:	Fair Products, Inc.

SECTION 2. HAZARDS IDENTIFICATION

b) Classification of the substance

GHS CLASSIFICATION IN ACCORDANCE WITH 29CFR1910 (OSHA HCS)

Irritating to skin (category 2), H315
May cause allergic skin reaction (category 1) H317
Causes serious damage to eyes (category 2A), H318
Specific target organ toxicity –single exposure (category 3), Respiratory system, H335
Aquatic acute toxicity (category 2), H401

For the full text of the H-Statements mentioned in this section, see Section 16

GHS LABEL ELEMENTS:

SIGNAL WORD: **DANGER**

HAZARD STATEMENTS

H315	causes skin irritation
H317	may cause allergic skin reaction
H318	causes serious damage to eyes
H335	may cause respiratory irritation
H401	toxic to aquatic life

PRECAUTIONARY STATEMENTS

P264	Wash skin thoroughly after handling.
P273	Avoid release into environment.
P280	Wear protective gloves/eye protection/face protection.
P302 & P352	IF ON SKIN: Wash with plenty of soap and water.
P305 & P351 & P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 & P313	If exposed or concerned: Get medical advice/attention.
P321	Specific treatment (see supplemental first aid instructions on this label).
P332 & P313	If skin irritation occurs: Get medical advice/attention.
P337 & P313	If eye irritation persists: Get medical advice/attention.
P362	Take off contaminated clothing and wash before reuse.
P403 & P233 P235	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up. Keep cool.
P501	Dispose of contents/container to an approved waste disposal plant.

Hazards not otherwise classified (HNOC) or not covered by GHS – None

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name:	n-decanol n-octanol
Common Name:	Fatty Alcohol Blend
Synonyms:	NONE
CAS-NO:	112-30-1 (n-decanol) 111-87-5 (n-octanol)
Weight Percent:	
n-decanol:	48.2%
n-octanol:	36.2%
Polyoxyethylene sorbitan monooleate/9005-65-6:	15.3%
Related compounds (dodecanol C-12) 112-53-8:	0.3%

SECTION 4. FIRST AID MEASURES

First aid procedures

Inhalation	If breathed in, move person to fresh air. If breathing has stopped artificial respiration should be started. Seek medical attention if symptoms develop.
Skin contact	Remove contaminated clothing. Wash thoroughly with soap and warm water. If irritation persists, seek medical advice/attention. Wash contaminated clothing before re-use.
Eye contact	Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Seek medical attention if irritation persists.
Ingestion	Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. DO NOT induce vomiting unless told to do so by a Poison Control Center or doctor. Never give anything by mouth to an unconscious or convulsing person.

SECTION 5. FIREFIGHTING MEASURES

Flammable properties

Flash point:	> 200°F

Firefighting

Suitable extinguishing media:	Water spray, carbon dioxide (CO_2), dry chemical or foam.
Unsuitable extinguishing media:	Do not use water jet, as this may spread burning material.
Firefighting procedures:	Protect against inhalation of combustion products. Assure self-contained breathing apparatus is worn. Prevent runoff if possible.
Further information:	Fight fires from a safe distance. Move containers from fire area if possible. Use water spray to cool unopened containers.
Protective equipment and precautions for firefighters:	Wear body covering protective clothing and self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	Ensure adequate ventilation. Wear suitable protective clothing, chemical resistant gloves, goggles, safety glasses or face shield. Avoid contact with skin and eyes.
Environmental precautions:	Prevent from entering sewer system, surface water or soil.
Methods for containment:	Absorb on an inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Methods for cleaning up:	Avoid dispersion of dust. Sweep up and collect in a suitable container for disposal.
Further information:	Keep in properly labeled containers.
Disposal:	Dispose of in accordance with Local, State and Federal Regulations.

SECTION 7. HANDING AND STORAGE

Handling Procedures:	Wear suitable protective clothing, gloves and eye/face protection. Avoid inhalation, ingestion and contact with skin and eyes. Handle and open container with care. Protect from contamination. Use only in well-ventilated areas. Wash thoroughly after handling. Keep container closed when not in use.
Requirements for Storage:	Store original containers away from direct heat, store in a cool, dry and well-ventilated area away from food, water and feed. Keep container tightly closed and maintain only in the original container.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines	Contains no substance with occupational exposure limit values.

Personal protective equipment

Eye protection:	Protective eyewear, such as goggles, safety glasses or face shield.
Hand protection:	Chemical resistant protective gloves.
Skin and body protection:	Long-sleeve shirt and long pants or coveralls. Rubber or plastic boots. Remove and wash contaminated clothing before re-use.
Respiratory protection:	Wear a dust respirator if dusting conditions exist.
Hygiene measures:	Observe good personal hygiene and safety practices. Avoid contact with skin, eyes or clothing. Wear chemical resistant gloves and eye/face protection. Do not inhale aerosol. Avoid prolonged inhalation of mists. Ensure adequate ventilation especially in confined areas. Do not eat, drink or smoke when using. Wash hands thoroughly after handling. Remove and wash contaminated clothing before re-use.

Engineering Controls

Ventilation:	General mechanical room ventilation is satisfactory for normal handling and storage operations.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

a) Appearance	
Form:	liquid
Color:	yellow
b) Odor:	characteristic alcohol odor
c) Odor Threshold:	No data available
d) pH:	7 - 8
e) Melting point/freezing point:	No data available
f) Initial boiling point and boiling range:	204 -238°C – (Technical)
g) Flash point:	>200°F
h) Evaporation rate:	No data available
I) Flammability (solid, gas):	Not applicable
j) Upper/lower flammability or explosive limits:	approximately 5.3% (v) / approximately 0.8% (v)- (Technical)
k) Vapor pressure:	0.66 mm Hg @ 24°C (Technical)
l) Vapor density:	4.5 – 5.5 (Technical)
m) Relative density:	0.85 gms/cc
n) Water solubility:	0.0035 g/ml @ 25°C (Technical)
o) Partition coefficient:	n-octanol/water: log POW: 2.3 – 4.2
p) Auto-ignition temperature:	260°C (Technical)
q) Decomposition temperature:	No data available
r) Viscosity:	14.9 CPS@ 25°C

SECTION 10. STABILITY AND REACTIVITY

g) Reactivity:	No data available
h) Chemical stability:	Stable at ambient temperatures and pressures.
i) Possibility of hazardous reactions:	Hazardous polymerization will not occur.
j) Conditions to avoid:	Excessive heat.
k) Incompatible materials:	Strong acids and bases; strong oxidizing agents.
l) Hazardous decomposition products:	Oxides of carbon and nitrogen.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute Oral Toxicity:	LD_{50} >5000 mg/kg (Rat)
Acute Dermal Toxicity:	LD_{50} >2000 mg/kg/bw (Rat)
Acute Inhalation Toxicity:	LC_{50} >2.09 mg/l (Rat)
Primary Skin Irritation:	Slightly irritating (Rabbit)
Primary Eye Irritation:	Extreme irritation (Rabbit)
Skin Sensitization:	Considered a contact dermal sensitizer at concentration of 25% and above (LLNA in mice). Not a sensitizer (Guinea Pig)

Carcinogenicity:

IARC	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
OSHA	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
NTP	No component of this product present at levels greater than or equal to 0.1% is identified as known or anticipated carcinogen by NTP.
ACGIH	No component of this product present at levels greater than or equal to 0.1% is identified as a potential carcinogen by ACGIH.

Toxicological Assessment

CMR Effects:	Carcinogenicity:	negative
	Mutagenicity:	negative
	Reproductive Toxicity:	negative

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity Effects

Toxicity to fish:	96 hours LC_{50} Rainbow trout: 20.4 ppm 96 hours LC_{50} Bluegill: 9.96 ppm
Toxicity to Daphnia and other aquatic invertebrates:	48 hour LC_{50} to Daphnia magna (water flea): 8.24 mg/l
Toxicity to birds:	Acute oral LD_{50} to Mallard Ducks: >4640 mg/kg/bw Eight Day Dietary LC_{50} to: Bobwhite Quail - >10,000 ppm Mallard Ducks - >10,000 ppm
Toxicity of honey bees:	48 hour contact LD_{50} >25 µg/bee

Elimination Information (persistence and degradability)

Biodegradability:	Readily biodegradable

SECTION 13. DISPOSAL CONSIDERATION

Further information:

Dispose of waste material in compliance with all federal, state and local regulations.
Avoid discharge to sewers and natural waterways.

Empty drums should be decontaminated and either passed to an approved drum reconditioned or destroyed. Containers that cannot be cleaned must be treated as waste.

SECTION 14. TRANSPORT INFORMATION

a) UN Number:	Not Regulated
b) UN Proper shipping name:	Environmentally hazardous substance, liquid, n.o.s.
c) Transport hazard class:	Not Regulated
d) Packing group:	Not Regulated
e) Marine Pollutant:	No
f) Transport bulk:	Not Regulated
g) Special precautions:	None

DOT
Not dangerous goods

TDG
Not dangerous goods

IATA
Not dangerous goods

IMDG
Not dangerous goods

RID
Not dangerous goods

SECTION 15: REGULATORY INFORMATION

OSHA Hazards	This material is hazardous under the criteria of the Federal OSHA Hazard Communication standard 29CFR 1910.1200.
SARA 302:	No chemicals in this material are subject to the reporting requirements for SARA Title III, Section 302.
SARA 311/312:	Acute Health Hazard.
SARA 313	This material does not contain any chemical components.
EPA FIFRA Information:	This chemical is a pesticide product registered by the U.S. EPA and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets (SDS), and for workplace labels of non-pesticide chemical. The hazard information required on the pesticide label is listed out below. The pesticide label also includes other important information, including directions for use.

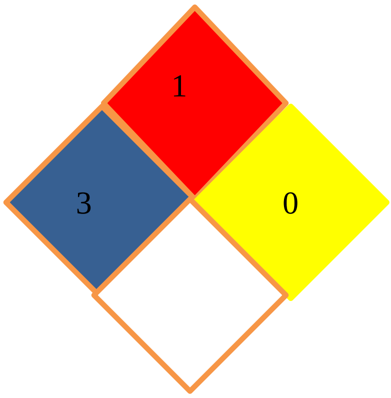
EPA / CERCLA Reportable Quantity:	None known

The components of this product are reported in the following inventories:

REACH	Not in compliance with the inventory.
CH INN	On the inventory, or in compliance with the inventory.
US. TSCA	On TASCA inventory.
DSL	All components of this product are in the Canadian DSL list.
AICS	On inventory or in compliance with the inventory.
NXIOC	On inventory or in compliance with the inventory.
ENCS	On inventory or in compliance with the inventory.
ISHL	On inventory or in compliance with the inventory.
KECI	On inventory or in compliance with the inventory.
PICCS	On inventory or in compliance with the inventory.
IECSC	On inventory or in compliance with the inventory.
TSCA list information:	US Toxic Substance Control Act (TSCA) Section 12 (b) Export Notification (40 CFR 707, Subpt D) ZUS T12B

SECTION 16. OTHER INFORMATION

HMIS Classification:	Health hazard: 3 Flammability: 1 Reactivity: 0
NFPA Classification: Fire hazard: 1	Health hazard: 3 Reactivity hazard: 0



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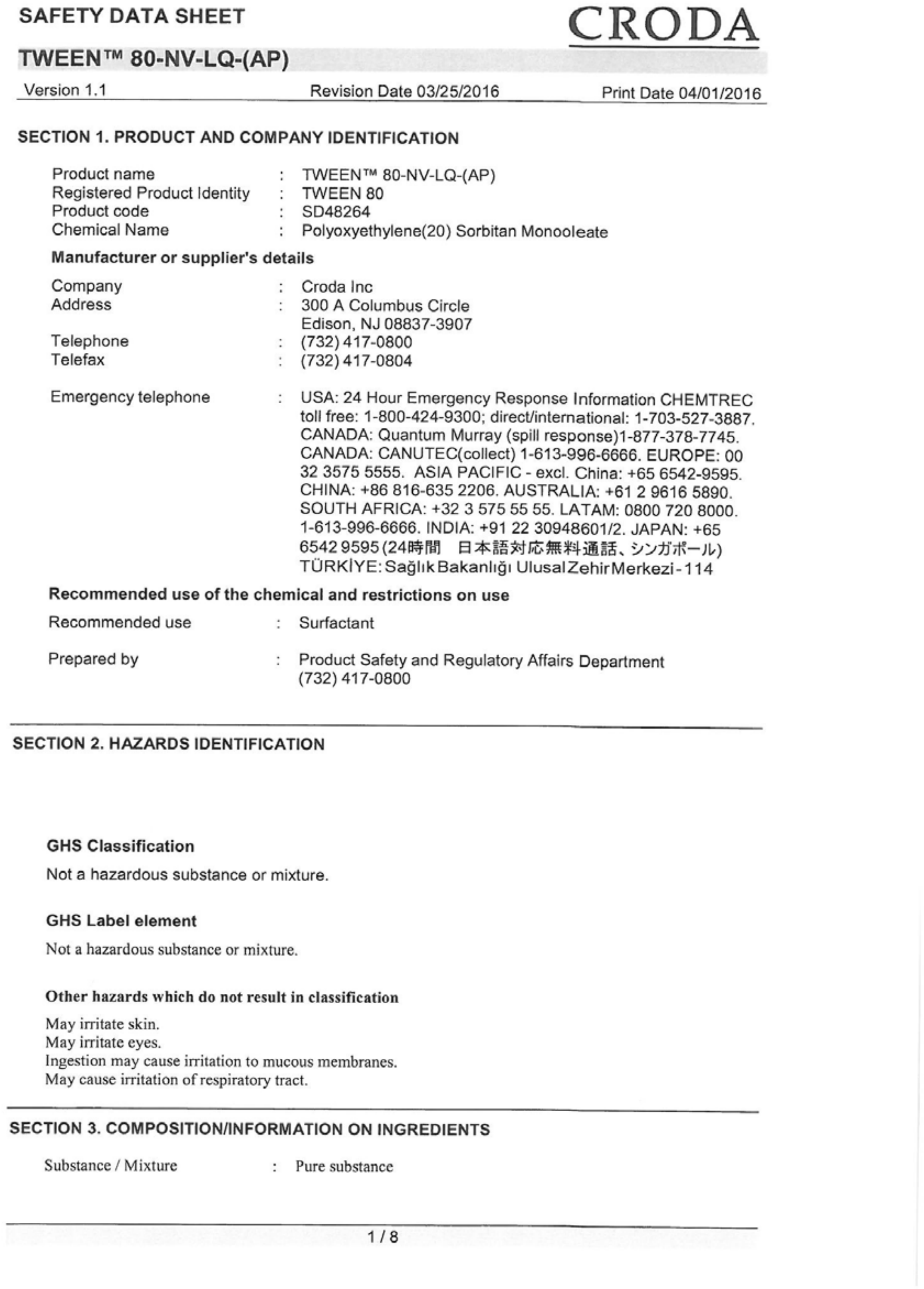


SAFETY DATA SHEET

CRODA

TWEEN™ 80-NV-LQ-(AP)

Version 1.1 | Revision Date 03/25/2016 | Print Date 04/01/2016

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	TWEEN™ 80-NV-LQ-(AP)
Registered Product Identity	:	TWEEN 80
Product code	:	SD48264
Chemical Name	:	Polyoxyethylene(20) Sorbitan Monooleate

Manufacturer or supplier's details

Company	:	Croda Inc
Address	:	300 A Columbus Circle Edison, NJ 08837-3907
Telephone	:	(732) 417-0800
Telefax	:	(732) 417-0804
Emergency telephone	:	USA: 24 Hour Emergency Response Information CHEMTREC toll free: 1-800-424-9300; direct/international: 1-703-527-3887. CANADA: Quantum Murray (spill response)1-877-378-7745. CANADA: CANUTEC(collect) 1-613-996-6666. EUROPE: 00 32 3575 5555. ASIA PACIFIC - excl. China: +65 6542-9595. CHINA: +86 816-635 2206. AUSTRALIA: +61 2 9616 5890. SOUTH AFRICA: +32 3 575 55 55. LATAM: 0800 720 8000. 1-613-996-6666. INDIA: +91 22 30948601/2. JAPAN: +65 6542 9595 (24時間　日本語対応無料通話、シンガポール) TÜRKİYE: Sağlık Bakanlığı Ulusal Zehir Merkezi - 114

Recommended use of the chemical and restrictions on use

Recommended use	:	Surfactant
Prepared by	:	Product Safety and Regulatory Affairs Department (732) 417-0800

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Not a hazardous substance or mixture.

GHS Label element

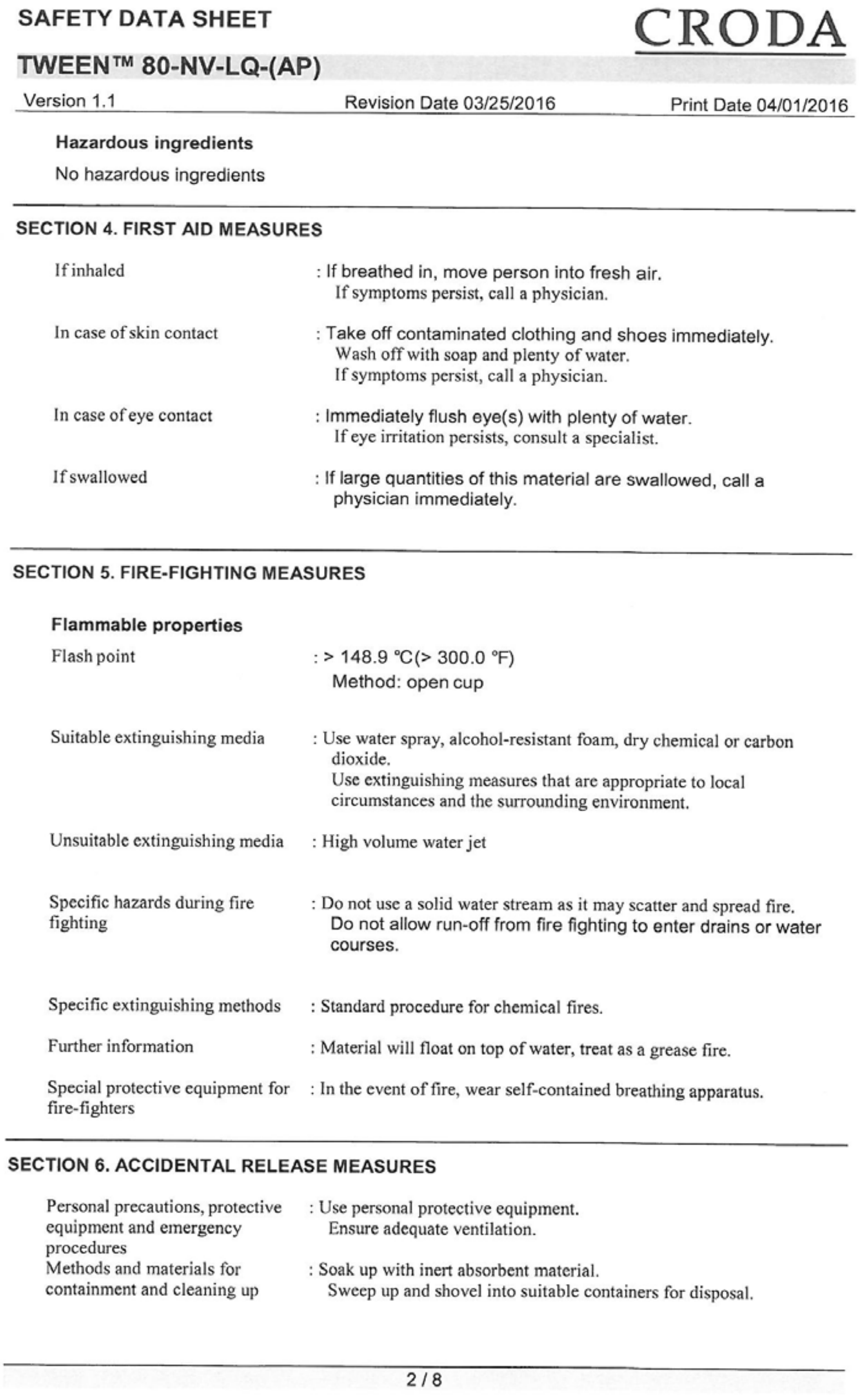
Not a hazardous substance or mixture.

Other hazards which do not result in classification

May irritate skin.
May irritate eyes.
Ingestion may cause irritation to mucous membranes.
May cause irritation of respiratory tract.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Pure substance



Hazardous ingredients

No hazardous ingredients

SECTION 4. FIRST AID MEASURES

If inhaled	: If breathed in, move person into fresh air. If symptoms persist, call a physician.
In case of skin contact	: Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water. If symptoms persist, call a physician.
In case of eye contact	: Immediately flush eye(s) with plenty of water. If eye irritation persists, consult a specialist.
If swallowed	: If large quantities of this material are swallowed, call a physician immediately.

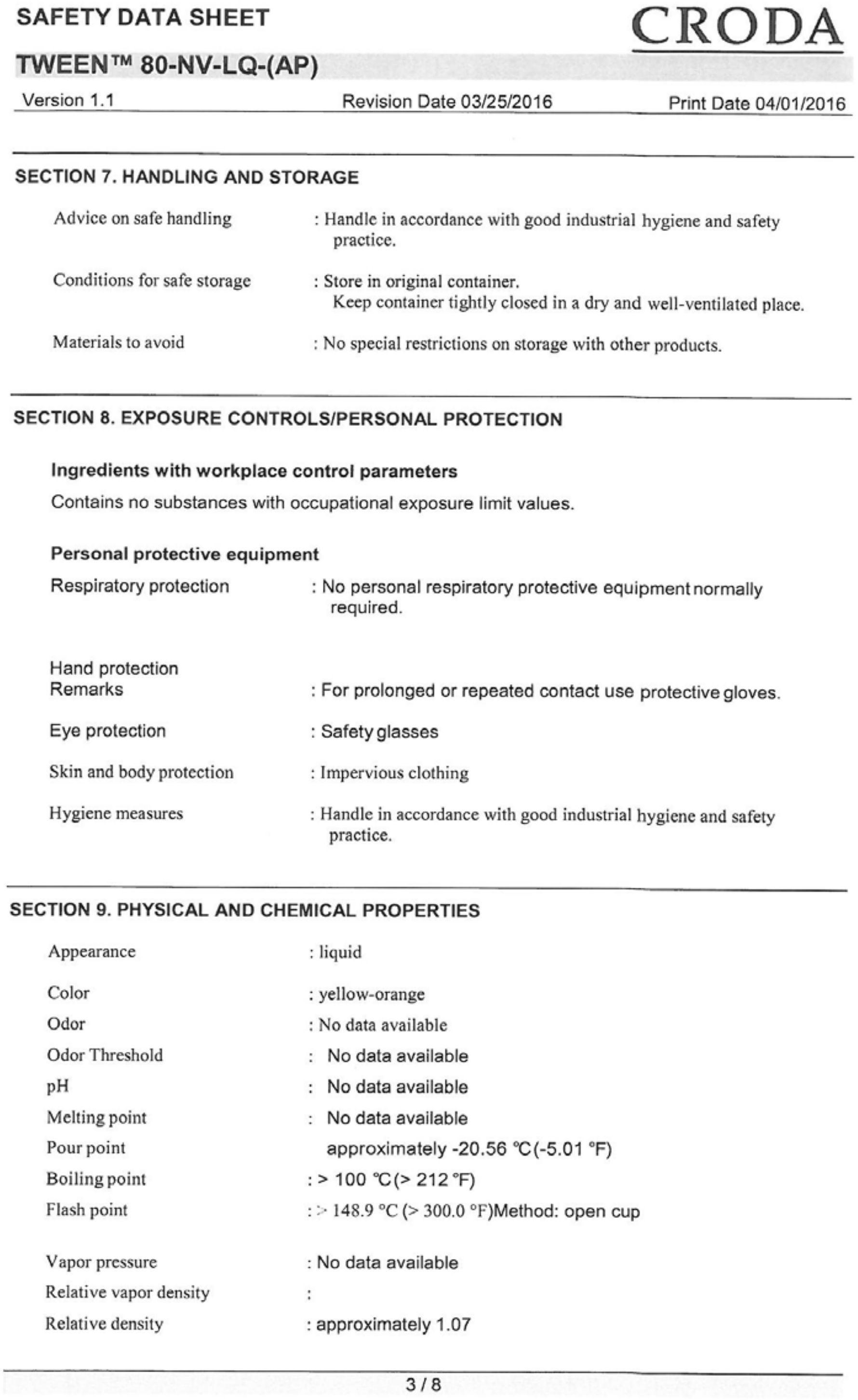
SECTION 5. FIRE-FIGHTING MEASURES

Flammable properties

Flash point	: > 148.9 °C(> 300.0 °F) Method: open cup
Suitable extinguishing media	: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	: High volume water jet
Specific hazards during fire fighting	: Do not use a solid water stream as it may scatter and spread fire. Do not allow run-off from fire fighting to enter drains or water courses.
Specific extinguishing methods	: Standard procedure for chemical fires.
Further information	: Material will float on top of water, treat as a grease fire.
Special protective equipment for fire-fighters	: In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Use personal protective equipment. Ensure adequate ventilation.
Methods and materials for containment and cleaning up	: Soak up with inert absorbent material. Sweep up and shovel into suitable containers for disposal.



SECTION 7. HANDLING AND STORAGE

Advice on safe handling : Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage : Store in original container.
Keep container tightly closed in a dry and well-ventilated place.

Materials to avoid : No special restrictions on storage with other products.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection
Remarks : For prolonged or repeated contact use protective gloves.

Eye protection : Safety glasses

Skin and body protection : Impervious clothing

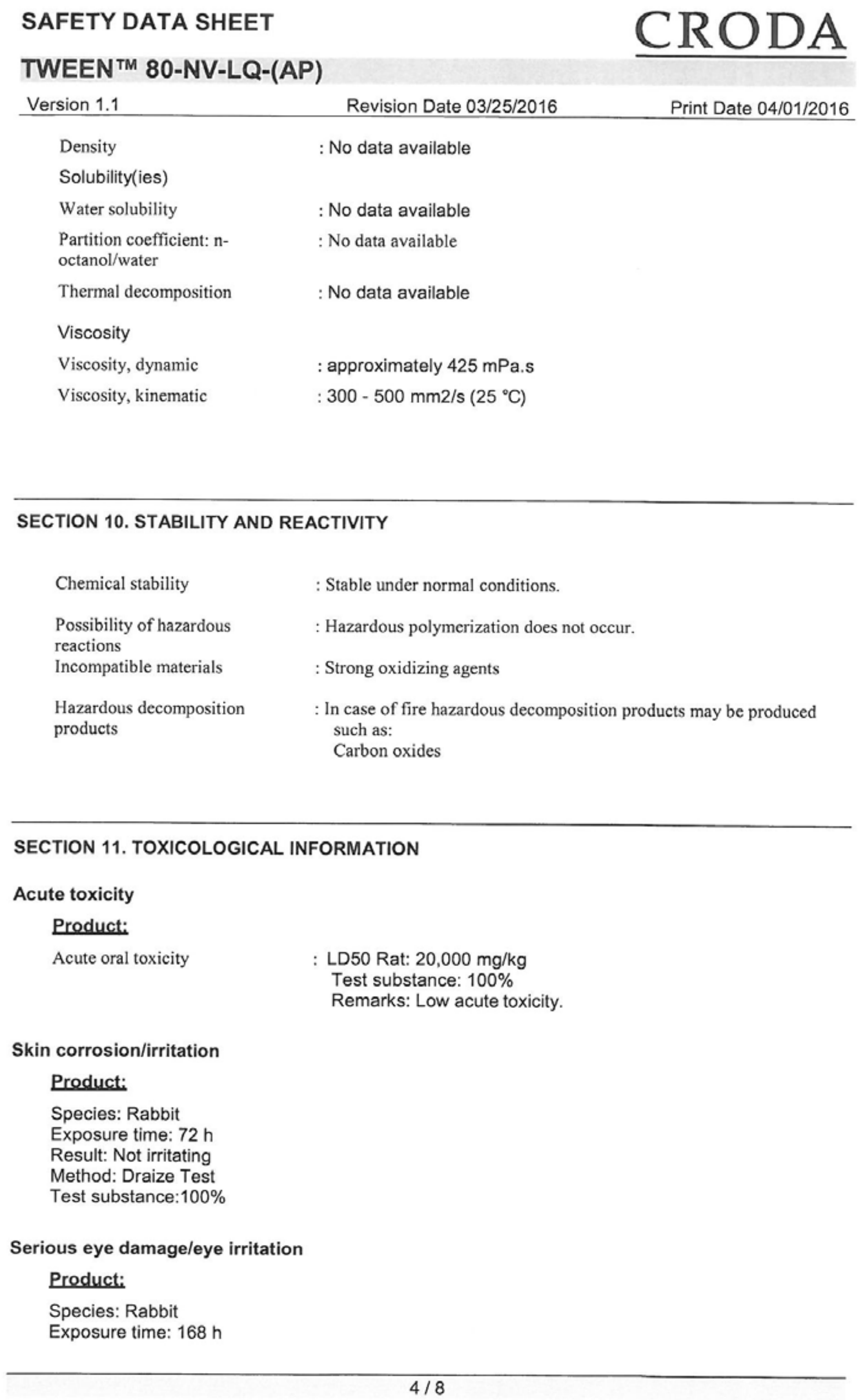
Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : yellow-orange
Odor : No data available
Odor Threshold : No data available
pH : No data available
Melting point : No data available
Pour point approximately -20.56 °C(-5.01 °F)
Boiling point : > 100 °C(> 212 °F)
Flash point : > 148.9 °C (> 300.0 °F)Method: open cup

Vapor pressure : No data available
Relative vapor density :
Relative density : approximately 1.07



Density	: No data available
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Thermal decomposition	: No data available
Viscosity	
Viscosity, dynamic	: approximately 425 mPa.s
Viscosity, kinematic	: 300 - 500 mm2/s (25 °C)

SECTION 10. STABILITY AND REACTIVITY

Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: Hazardous polymerization does not occur.
Incompatible materials	: Strong oxidizing agents
Hazardous decomposition products	: In case of fire hazardous decomposition products may be produced such as: Carbon oxides

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity	: LD50 Rat: 20,000 mg/kg Test substance: 100% Remarks: Low acute toxicity.

Skin corrosion/irritation

Product:

Species: Rabbit
Exposure time: 72 h
Result: Not irritating
Method: Draize Test
Test substance:100%

Serious eye damage/eye irritation

Product:

Species: Rabbit
Exposure time: 168 h

Result: Not irritating
Method: Draize Test
Test substance: 100%

Respiratory or skin sensitization

Product:

Species: Humans
Result: Patch test on human volunteers did not demonstrate sensitization properties.
Test substance: 100%

Germ cell mutagenicity

No data available

Carcinogenicity

No data available

Reproductive toxicity

No data available

STOT-single exposure

No data available

STOT-repeated exposure

No data available

Aspiration toxicity

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

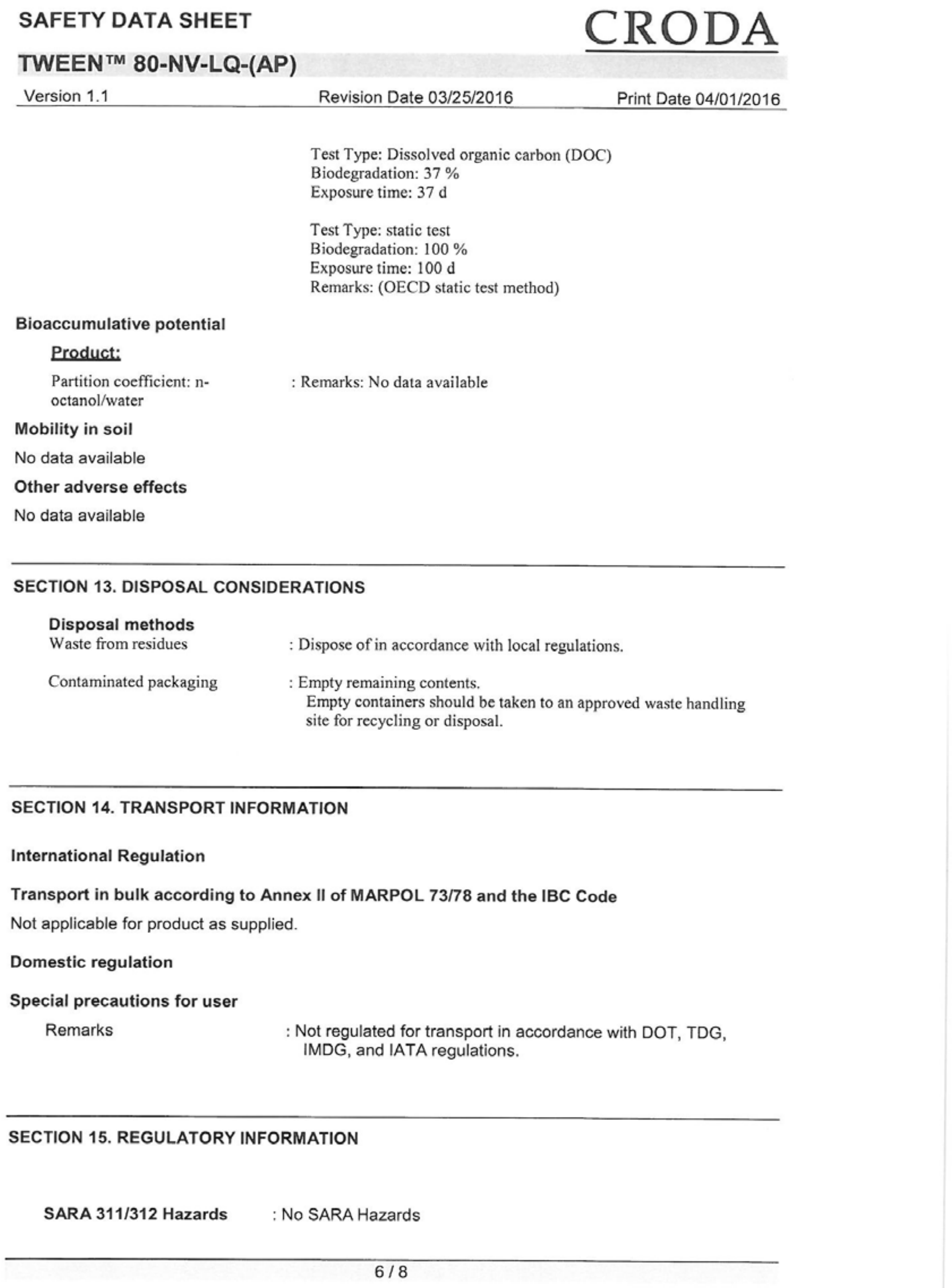
Product:

Toxicity to fish	: LC50 (Oncorhynchus mykiss (rainbow trout)): 471 mg/l Exposure time: 96 h Test Method: static test Method: static test
Toxicity to daphnia and other aquatic invertebrates	: LC50 (Mysidopsis bahia): 165 mg/l Exposure time: 96 h Test Method: static test
Toxicity to bacteria	: IC0 (Pseudomonas putida): > 10,000 mg/l

Persistence and degradability

Product:

Biodegradability	: Test Type: (OECD 301C) Biodegradation: 52 % Exposure time: 52 d



Test Type: Dissolved organic carbon (DOC)
Biodegradation: 37 %
Exposure time: 37 d

Test Type: static test
Biodegradation: 100 %
Exposure time: 100 d
Remarks: (OECD static test method)

Bioaccumulative potential

Product:

Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	: Dispose of in accordance with local regulations.
Contaminated packaging	: Empty remaining contents. Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

International Regulation

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

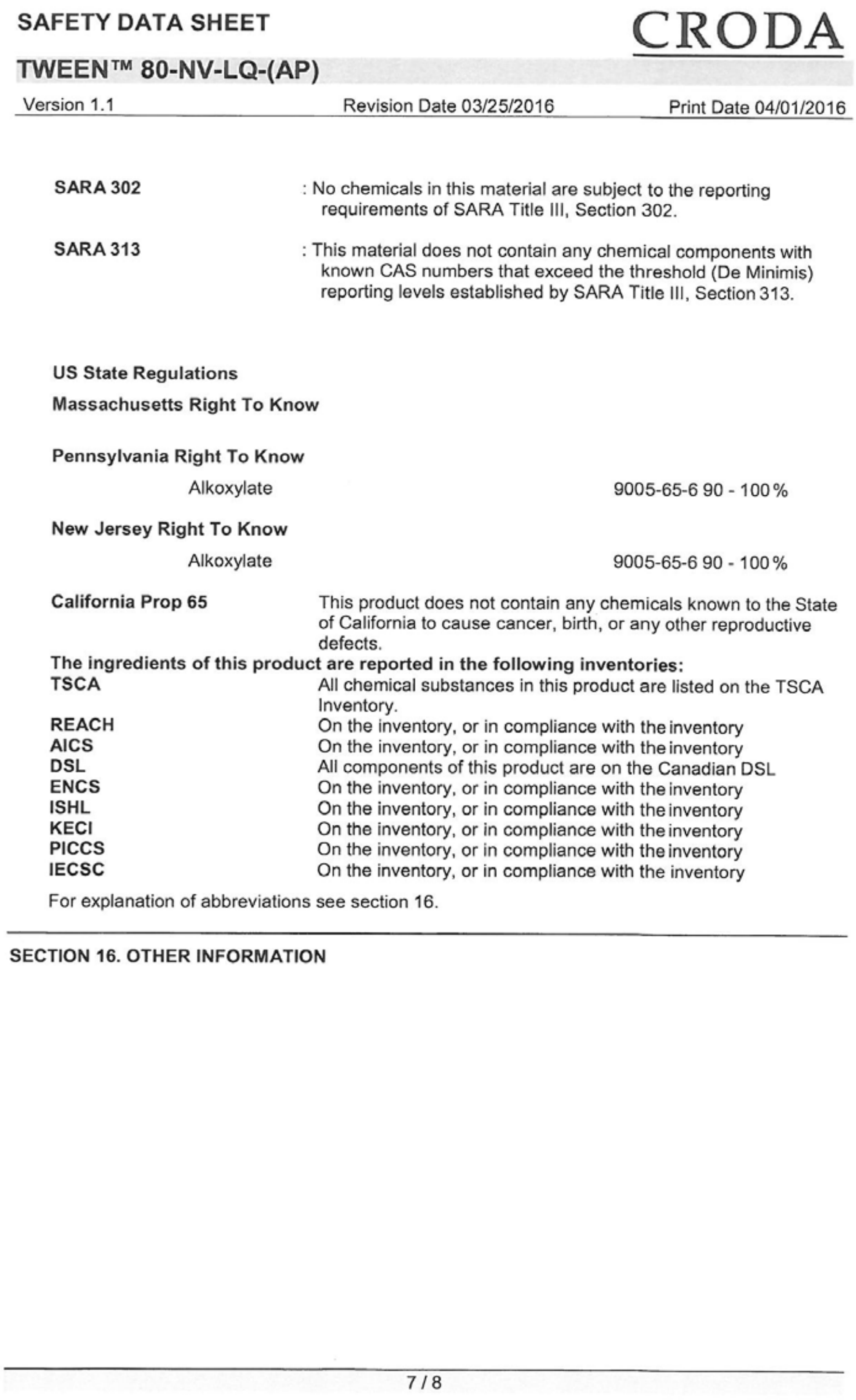
Domestic regulation

Special precautions for user

Remarks : Not regulated for transport in accordance with DOT, TDG, IMDG, and IATA regulations.

SECTION 15. REGULATORY INFORMATION

SARA 311/312 Hazards : No SARA Hazards



SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Massachusetts Right To Know

Pennsylvania Right To Know

Alkoxylate	9005-65-6 90 - 100 %

New Jersey Right To Know

Alkoxylate	9005-65-6 90 - 100 %

California Prop 65 This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

The ingredients of this product are reported in the following inventories:

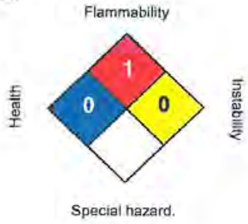
TSCA	All chemical substances in this product are listed on the TSCA Inventory.
REACH	On the inventory, or in compliance with the inventory
AICS	On the inventory, or in compliance with the inventory
DSL	All components of this product are on the Canadian DSL
ENCS	On the inventory, or in compliance with the inventory
ISHL	On the inventory, or in compliance with the inventory
KECI	On the inventory, or in compliance with the inventory
PICCS	On the inventory, or in compliance with the inventory
IECSC	On the inventory, or in compliance with the inventory

For explanation of abbreviations see section 16.

SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS II:

HEALTH	0
FLAMMABILITY	1
Reactivity	0

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Key or legend to abbreviations and acronyms used in the safety data sheet

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TCSI (Taiwan), TSCA (USA)

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

ITEM B.12 Research information

The following reports are included:

a. Literature Review on Fatty Alcohol Compunds; Lab Project Number FATF-9101; Compliance Services International; November 15, 1991; 60 pp.

b. Reregistration Eligibility Decision (RED) for Aliphatic Alcohols; US EPA Document EPA 738-R-07-004, March 2007.

c. R.E.D. FACTS Aliphatic Alcohols

d. Aliphatic Alcohols: Human Health Chapter of Reregistration Eligibility decision (RED) dococument Reregistration Case Number 4004, June 30, 2006.

MRID 42135801

MONOGRAPH

Literature Review on Fatty Alcohol Compounds

REPORT DATE
November 15, 1991

PROJECT NUMBER
FATF-9101

REPORT AUTHOR
Bernalyn D. McGaughey, Compliance Services International

DATA REQUIREMENTS
Pesticide Assessment Guidelines, Subdivision N, Sections
160-5, 161-1, 161-2, 161-3, 162-1, 162-3, 163-1, 164-1, 165-4

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I. ABSTRACT

The scientific data bases available by on-line access to the Dialog Information Services were searched for information on fatty alcohols and their behavior in the environment. The data reviewed and presented here support many of the basic assumptions of fatty acid metabolism and straight-chain carbon compound breakdown. Fatty alcohols have been investigated as biomarkers, because they are associated with virtually every life form. Different species have different ranges of chain-length alcohols, and are variously able to transform these products into shorter or longer-chain fatty acids, ketone, glycols or other compounds which are natural components of living organisms.

The fate and metabolism of straight-chain fatty alcohols is explained by basic biochemical principals. The compounds of interest in tobacco sucker control are short chain fatty alcohols, primarily C_8 and C_{10} normal alcohols, with small amounts of C_6 and C_{12} normal alcohols. Many of the articles reviewed dealt with chain lengths above and below this number, or with iso- or antesio-chains; some investigations on fatty alcohol detergents have valuable information, but dealt with fatty alcohol ethoxylates.

While no reviewed information addresses the classical requirements of the EPA guidelines for environmental fate testing, there does appear to be some information available which allows the prediction of the behavior of n-fatty alcohols of C_6 to C_{12} chain length. Basic breakdown in all systems is by 2-carbon oxidation, followed by mineralization or use of the components in fatty acid synthesis pathways.

II. INTRODUCTION

As requested by the EPA in Dr. Allan S. Abramson's letter to Harley D. Hathaway of Cochran Corporation (August 21, 1991), a literature search was conducted to address the environmental fate aspects of the FIFRA Section N Guidelines for Pesticide Registration. A search of on-line data through Dialog Information Services was conducted on September 8, 1991. The "science and technical files" of Dialog were searched (120 files). No effort was made to limit this search by alcohol chain length or nature. There were 11,456 citations available on fatty alcohol compounds. In order to develop a reasonable list of citations, terms related to environmental fate were used to narrow down the number of "hits" on the data system. A print-out of 677 citations was the result of this search process; many of the citations had abstracts included. Particularly relevant articles, which were available in the English language, were obtained for review.

Where abstracts presented relevant information, but the article was either not directly related to our investigation or was published in a language other than English, appropriate excerpts of the abstract were noted in a bibliography. Full copies of articles were reviewed and built into the bibliography on fatty alcohols. Lastly, articles which were described or cited by authors whose publications are reviewed here (secondary references) were included in the bibliography as possible further source documents. Time did not allow the procurement of secondary references. It is important to include these publications in our list, since much of the research on fatty alcohols was elementary in that the predictability of the behavior of the compound is based on early biochemical discoveries related to the metabolism and global recycling of organic carbon compounds. All references found to be relevant (abstracts, reviewed articles and secondary references) are included in the appendix of this document.

The body of this document is arranged by guideline number, in accordance with the data requirements this monograph was intended to address. As might be expected, no publications approached fatty alcohol fate in a typical FIFRA-guideline testing manner. The findings of various authors do corroborate one another and can lead to a basic understanding of the behavior of normal (or straight chain saturated) fatty alcohols.

III. GENERAL INFORMATION

Mixtures of C_8 and C_{10} fatty alcohols are used in the "desuckering" of tobacco. The "technical product" consists of a distillation cut within the range of alcohols which (1) show significant activity for the use intended and (2) are not phytotoxic to mature tobacco foliage. The "formulated products" and the technical product usually include small amounts of C_6 and C_{12} alcohols, and the end use product includes the addition of polyoxyethylene (20) sorbitan mono-oleate (SMO). Fatty alcohols are applied as emulsions and in tobacco act as plant growth regulators by desiccating small axillary growth. They are not translocated but instead destroy the tissue at the point of contact (Wheeler, Seltman and Motten, 1991).

Fatty alcohols for use in tobacco sucker control are from natural and synthetic sources. The process of manufacture or isolation of the chain lengths of interest is by one of two means: hydrogenation of natural raw materials, such as coconut oils or palm kernel oils or the Zigler alcohol process which uses petrochemical feedstocks. The fatty alcohols synthesized by the Zigler processes are structurally similar to natural fatty alcohols (Noweck, 1987). These processes are the most appropriate for providing the basic ingredients of sucker control agents due to their production of materials which are high in purity and due to the range of chain-lengths obtained.

In the following discussions, several synonyms for primary alcohols will be used interchangeably. These are: n-fatty alcohols, 1-xxxxol (where xxxx is the description of the chain length), straight-chain alcohols, [normal] aliphatic alcohols and saturated alcohols. For ease in identification of the nomenclature which relates to various chain lengths, see Table 1.

This review concentrates on information available on n-fatty alcohols of "lower" chain lengths (6 to 16 carbons). Most research shows that the behavior of these compounds in *the environment is similar due to the manner in which the molecule is attacked and with* which it binds to soil. Soil microorganisms readily incorporate fatty alcohols into their nutrient assimilation cycles (Buning-Pfaue and Rehm, 1972). Birds, fish and mammals can ingest or digest these compounds or more complex compounds with fatty alcohol components without adverse effects (Noweck, 1987; Place and Roby, 1986; Obst, 1986; Prahl, Eglinton and Corner, 1985).

Some very valuable information comes from studies conducted on biodegradable detergents which are based on fatty alcohol. These studies followed the fate of the ring compounds as well as the fate of the straight-chain alcohols and used radiolabeled tracers to identify those components. The findings confirm the assumptions that basic 2-carbon oxidation and fatty alcohol assimilation or mineralization is rapid and complete, without the formation of exotic metabolites.

IV. SECTION N GUIDELINES, 160-5: CHEMICAL IDENTITY

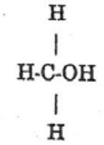
Fatty alcohols are aliphatic alcohols with chain lengths between C6 and C_{22}; alcohols with a chain length above C_{22} are referred to as "wax alcohols". Coconut ("natural") alcohols produce very few impurity peaks and contain less than 0.1% n-tridecanol and varying amounts of n-alkanes. Zigler alcohols are primary, straight chain alcohols with an even carbon number. Gas chromatography shows up to 1.0% impurities, consisting of numerous even-numbered, isomeric fatty alcohols (Noweck, 1987).

The compounds used in tobacco sucker control predominantly contain C_8 (1-octanol) and C_{10} (1-decanol), which are considered the effective ingredients in sucker control. The presence of C_6 and C_{12} are partly due to artifact and partly due to their contribution to the desiccation properties of the product. Saturated fatty alcohols up to 1-dodecanol (C_{12}) are clear, colorless liquids with a lower specific gravity than water. The lower members of the series have a characteristic odor. Boiling points and melting points increase uniformly with chain length. There are no gaseous alcohols. Sinniah (1983) reports a melting point value for 1-decanol which is significantly different from that reported by Noweck (-26.6° vs. 7°C, respectively). The influence of the polarizing hydroxyl group diminishes with chain length; thus hexanol and even octanol show some water solubility, but decanol is immiscible with water. Fatty alcohols are soluble in common organic solvents such as petroleum ether, lower alcohols, and diethyl ether (Noweck, 1987).

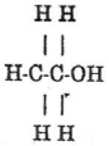
Available details on the production, properties and nomenclature of fatty alcohols are given in Tables 1, 2, 3 and 4 and in Figure 1. Approximately 60% of the fatty alcohols produced are based on petrochemicals. Price fluctuation in raw materials (natural versus petrochemical) could affect the future distribution of the use of these two raw materials. Fatty alcohols and their derivatives are used in synthetics, surfactants, oil additives and cosmetics (Noweck, 1987), as well as in the uses being supported by this review.

In Chemistry for Agriculture and Ecology, the author makes the following presentation regarding general organic chemistry:

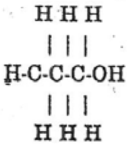
> In spite of the large number of known organic compounds, it is not necessary to examine the properties and reactions of each compound individually. Instead, organic compounds can be classified into a few *homologous series* of closely related compounds with similar properties and reactions. For example, the series of compounds



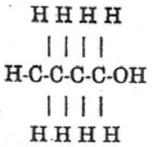
$\mathrm{H}-\underset{\mathrm{H}}{\overset{\mathrm{H}}{\mathrm{C}}}-\mathrm{OH}$



$\mathrm{H}-\underset{\mathrm{H}}{\overset{\mathrm{H}}{\mathrm{C}}}-\underset{\mathrm{H}}{\overset{\mathrm{H}}{\mathrm{C}}}-\mathrm{OH}$



$\mathrm{H}-\underset{\mathrm{H}}{\overset{\mathrm{H}}{\mathrm{C}}}-\underset{\mathrm{H}}{\overset{\mathrm{H}}{\mathrm{C}}}-\underset{\mathrm{H}}{\overset{\mathrm{H}}{\mathrm{C}}}-\mathrm{OH}$



$\mathrm{H}-\underset{\mathrm{H}}{\overset{\mathrm{H}}{\mathrm{C}}}-\underset{\mathrm{H}}{\overset{\mathrm{H}}{\mathrm{C}}}-\underset{\mathrm{H}}{\overset{\mathrm{H}}{\mathrm{C}}}-\underset{\mathrm{H}}{\overset{\mathrm{H}}{\mathrm{C}}}-\mathrm{OH}$

> is a homologous series of *alcohols*, each containing the hydroxyl (OH) *functional group* attached to a hydrocarbon chain of varying length. As we shall see in chapter **12, hydrocarbon chains tend to be chemically inert** [emphasis added] and, therefore, the chemical properties of alcohols depend mainly upon the hydroxyl functional group. Consequently, we can establish generalizations about the properties of alcohols by studying a few representative members of the series. (Hay, 1981)

Hay notes further that the length of the chain has a small effect on the chemical properties of the compound, but can have a large effect on the physical properties of the compound, such as melting point, boiling point and solubility (as we see in the information from Noweck, 1987). The high temperatures for changes of state and the high water solubilities of C_1-C_5 alcohols are due to the formation of strong hydrogen bonds between hydroxyl groups of the molecules and water molecules. However, as the hydrocarbon chain becomes longer, its hydrophobic properties dominate. This dominance is generally reported to occur at a chain length of 10 carbons.

Alcohols are very weak acids. For their ionization, K_a values vary from 10^{-13} to 10^{-18}, depending upon the length of the carbon chain. Primary alcohols are oxidized by strong oxidizing agents, such as potassium dichromate or potassium permanganate, and yield first aldehydes and subsequently carboxylic acids. Alcohols react with carboxylic acids to give esters; for example, ethanol reacts with acetic acid to give ethyl acetate. Alcohols may also be "condensed to form carbohydrates or other more complex molecules. Primary alcohols are very basic building blocks of organic molecules, and without biological processes or extreme conditions not found in the environment, n-fatty alcohols would be expected to be generally inert.

V. SECTION N GUIDELINES, 161-1: HYDROLYSIS

Hydrolysis studies reported in the literature are based on studies which utilize more complex compounds than normal saturated fatty alcohols. Lindstedt (1990) reported that fatty alcohol esters hydrolyze and produce normal human metabolites. The fate or action of hydrolysis on the chain itself was not discussed in the abstract which was reviewed; contents of the abstract suggested that the information was not directly relevant to the range and character of alcohols in which we have an interest.

In studies by Hosotani, Ohkochi and Inui (1988), there was no apparent interference from hydrolysis when the photoassimilation of fatty alcohols was studied in *Euglena gracilis* Z. Experiments were run in both light and dark conditions; in studies using sucrose as the nutrient source, hydrolysis of sucrose was reported to have interfered. No such mention was made for the studies conducted with fatty alcohols as a carbon source. *Euglena* cultures were maintained for up to 14 days.

The properties of fatty alcohol as displayed by the available literature suggest that hydrolysis is not a major degradation pathway for n-aliphatic alcohols. The behavior of lower chain (C_2 to C_8) alcohols in water-based formulations and their use as solvents in so many arenas suggest that decomposition by hydrolytic means is not a factor. The influence of the polarizing hydroxyl group, which in turn influences miscibility, diminishes with chain length (Noweck, 1987). The use of octanol in the FIFRA guideline study which determines an "octanol/water partition coefficient" is also a statement toward the stability of octanol under sterile solution conditions.

VI. SECTION N GUIDELINES, 161-2: PHOTODEGRADATION - WATER

No specific studies on the photodegradation of fatty alcohols in water were discovered in this literature search. Some conclusions can be drawn from the conditions reported in other types of investigations.

Peltzer and Gagosian (undated) compared concentrations of fatty alcohols in air and rainwater samples in order to test the efficiency of their sampling and analytical methods. Their interest was in the analysis of fatty alcohols and their use as biomarkers. No report of interference due to breakdown in water was given in the abstract reviewed here.

The single study found that specifically dealt with hydrolysis assessed breakdown by titration, with the experimentation being conducted on fatty alcohol esters (Brown, 1983). Since specific breakdown products were not identified, and the parameters of the test were far from those of "natural" conditions, the study provided no additional data specific to n-fatty alcohols.

The fact that marine and riverine surface sediments and oceanic surface samples contain fatty alcohols and acids which reflect the nature of life or organic carbon sources they contain (Sargent, et. al., 1983; Romankevich et. al., 1982; Garrett, 1964) also supports the thesis that these compounds do not degrade readily by photolysis.

The information above suggests that photodegradation of n-fatty alcohols in water is minimal and is not a major pathway for compound degradation.

VII. SECTION N GUIDELINES, 161-3: PHOTODEGRADATION - SOIL

As with the literature citations on photolysis in water, no studies were found which specifically dealt with this aspect of fatty alcohol behavior. Many researchers have undertaken to utilize fatty alcohols as biomarkers in identifying the origin of ancient sediments and in identifying the airborne sources of carbon compounds (Sargent et. al. (1983); Simoneit (1989); Simoneit and Mazurek (1982); Currie and Johns (1989); Venkatesan and Kaplan (undated); Sever and Parker (1969)). These researchers have found that the distribution of fatty alcohols and fatty acids in the samples collected are in many cases representative of the distribution of life forms which created the sediment or particulate matter dispersed throughout the associated environment. These similar "fingerprints" suggest that these compounds are relatively stable when not being cycled through a living organism. The presence of fatty alcohols in sedimentary rocks and in uncontaminated soils (Hoering (1969); Ambles (1991)) further supports this thesis.

The findings reported above on use of fatty alcohols as biomarkers or as origin-markers suggest that degradation in soil would not be expected in the absence of microbiological activity and photolysis in soil is not a major degradation pathway.

VIII. Section N Guidelines, 162-1: Aerobic Soil Metabolism

Several investigators have worked with isolated soil organisms to determine the ability of such organisms to degrade fatty alcohol or to use it as a food source. In experiments by Buning-Pfaue and Rehm (1972), *Pseudomonas aeruginosa* was able to produce fermentation products based on the use of decanol as a sole source of nutrients. His findings suggested that soil microorganisms of this type readily incorporate fatty alcohols into their nutrient assimilation cycles.

The commercial production of detergents and biosurfactants has lead to research on fermentation which includes experimentation with organisms isolated from the soil. Bacteria, yeast and fungi grown on basic carbon sources can synthesize fatty acids, glycerides, phospholipids, lipopeptides and antibiotics. Singer and Finnerty (1990) report that biosurfactants produced by microorganisms are generally considered to represent a mechanism for the solubilization or emulsification of water-insoluble substrates to facilitate transport by cells. Their investigation describes the identification of a biosurfactant-producing bacterium and the general physiology of biosurfactant synthesis. The organism studied is *Rhodococcus species* H13-A, which was isolated from soil after several passages on hexadecane (C_{16}) enrichment medium.

In general, biological assimilation of primary alkanes and alcohols would be expected to be similar. Of interest in the Singer and Finnerty work is their experiments to determine the growth rate of the isolated soil organism on various carbon sources. Among the compounds they investigated were straight chain alkanes. Extracellular glycolipid synthesis by *Rhodococcus* occurred when the carbon source was decane (C_{10} through C_{18}). Other studies were referenced which reported glycolipid synthesis by actinomycete during growth on alkanes.

Ambles, et. al, 1991, noted that soil lipids include a great number of neutral or acid components (including fatty alcohols). These he classed as "simple lipids"; the unknown, **barely soluble fraction was reported as complex lipids or the "polar fraction" of the soil** lipid components. Ambles observed that the experimental work of others (and his work) "suggested that the soil polar fraction may correspond to a polar matrix (a biopolymer) which can 'react' with simple lipids, [with] the process of incorporation of simple lipids being reversible in biologically active soils."

In his work, Ambles compared the simple lipids in the soil to breakdown products of the "polar fraction". Even carbon number, straight chain fatty alcohols were found in soils from the two locations he tested. His work showed that the distribution of simple lipids was fairly similar to the products derived from the breakdown of the polar fraction and that his initial premise may be valid. This work provides evidence that microbially active soil has an existing metabolic pathway for the immediate incorporation of short-chain fatty alcohols such as those used in tobacco sucker control. Since components of the formulation are already naturally present in the soil, microbial metabolism may be expected to proceed rapidly, with the use of C_8 and C_{10} normal alcohols as a food source.

Fatty alcohol based detergents and surfactants have been shown to degrade thoroughly and completely in the environment (Steber, et. al, 1988; Richterich et. al, 1985). Steber reported generally that this group of detergents showed a very rapid and complete biodegradation under both aerobic and anaerobic conditions with respect to primary breakdown and ultimate degradability (mineralization and assimilation). Richterich reported a biodegradability (the German BiAs reduction test) of 93% to 98% for a C_{12}/C_{18} based fatty alcohol detergent.

The straight chain fatty alcohol sulfates (detergents), whether derived from natural alcohols, natural fats or oils, or from ethylene by Zigler-type processes, are generally considered to be completely biodegradable (Speel, 1963).

The relationship of the above articles to the degradation of fatty alcohol will be discussed further in Section IX (Anaerobic Aquatic Metabolism); investigations with [1-^{14}C]-stearyl alcohol ethoxylate and EO-labeled compound further identify the specific behavior of the alkyl portion of that compound. Two Italian language articles were not translated which could support further the microbial breakdown of aliphatic alcohols (Sabastiani et. al, 1971). Work by Langley (1970), which investigated the properties of monolayer films in connection with their proposed use as evaporation control agents, is also reported in the next section. The work reported in that section reinforces the assumption that metabolism of fatty alcohols in soil is rapid and complete and without the formation of exotic metabolites.

IX. SECTION N GUIDELINES, 162-3: ANAEROBIC AQUATIC METABOLISM

The aerobic and anaerobic degradation of fatty alcohol-derived detergents has been well reported in published literature. Since some of these studies follow the fate of the fatty alcohol moiety, they are valuable to our understanding of the aquatic metabolism of these compounds. Fatty alcohols are generally accepted as biodegradable under both aerobic and anaerobic conditions (Steber, et. al, 1988) and will be used as a carbon source by the microorganisms which occupy those respective environments. The pathway of incorporation and the assimilated products may vary based on many environmental factors, but all assimilated products will be typical compounds found in the fatty acid synthesis process which is basically "common" to all life forms.

The articles reviewed below give credence to the statement made above. They also provide some evidence of the possible end points which would be typical in a classical FIFRA guideline study on aerobic or anaerobic aquatic metabolism.

Hosotani, et. al (1988) conducted a series of investigations in the aquatic protozoan, *Euglena gracilis* Z. The assimilation of fatty alcohols and other carbon sources by *Euglena gracilis* Z. was investigated by studying the growth of the organism and its photoassimilation of these compounds. *E. gracilis* Z and its streptomycin-bleached mutant from established stock cultures were exposed to growth media containing 0.2% fatty alcohols (carbon chain lengths of 1 to 20).

E. gracilis growth varied depending upon the chain length of the alcohols included in the culture medium. 1-dodecanol (C_{12}), 1-tridecanol (C_{13}), and 1-tetradecanol (C_{14}) supported considerable growth under illumination. Assimilation of dodecanol and tetradecanol for growth strictly depended upon light. The fatty alcohols C_5-C_{11} inhibited growth, while methanol and the alcohols C_{15}-C_{20} did not support growth. The growth pattern of *E. gracilis* on fatty alcohol is shown in Figure 2.

The mechanism of photoassimilation of C_{14}-alcohol (myristyl alcohol) was strictly light dependent; however, DCMU, an inhibitor of photosynthetic electron transfer, did not inhibit growth completely. With the bleached mutant *Euglena*, a long lag-phase extending more than 10 days occurred before growth started under illumination, and the final cell yield was about half that observed with wild-type cells. Growth on myristyl alcohol was almost saturated at light intensities of 600-1000 lx in comparison to autotrophic growth which increased with light intensities to at least 2000 lx.

The reason for variance in growth rates from one compound to another was not clear. The alcohols with chain lengths of 5 to 11 carbons inhibited photoautotrophic growth completely, and killed the cells. Other varieties of *Euglena gracilis* have been reported to grow on these middle carbon-chain-length alcohols.

The results of the photoassimilation experiments show that photosynthetic energy is not completely necessary for the photoassimilation of the alcohol. Shading of *Euglena* growing on myristyl alcohol may have caused the accumulation of paramylon and lowered synthesis of amino acids and protein which are essential for the cell growth. The bleached mutant has been shown to adapt to myristyl alcohol medium after several transfers and an increase in $(NH_4)_2SO_4$ concentration. The mutant may induce an ability to synthesize amino acids from myristyl alcohols by this adaptation.

Steber and Wierich, in two publications (1983 and 1985), discuss the biodegradation of fatty alcohol ethoxylates. their work is particularly relevant to our interests here due to the labeling of both the alkyl chain and the ethoxylate in separate but parallel experiments. The [1-^{14}C] stearyl alcohol = 7 EO had a specific activity of 19.2 mCi/g; the radiochemical purity was 98%. Only the results of the experimentation conducted on the labeled alkyl compound is discussed here.

In the first publication (1983), the simulation tests used a model plant which was a miniature continuous flow activated sludge unit constructed according to Swisher. The die-away tests were discontinuous tests analogous to the OECD Screening Test and were performed in shake flasks modified to a closed system. In the simulated plant study, after a working-in period of approximately two weeks the plant was fed for about one week with synthetic sewage containing one of the radiolabeled surfactants. As expected, the carbon in the 1-position of the alkyl-labeled compound was mineralized to $^{14}CO_2$ to a greater extent than the EO-moiety of the analogous ^{14}C-EO surfactant. Mineralization rates were 50 to 60% after 2 to 3 days of ^{14}C-feeding, with a slightly increasing tendency. The radioactivity of the effluent from the alkyl-labeled surfactant only amounted to about 6% (undegraded). When results were adjusted for recovery (93.8%), it was reported that 99% of the fatty alcohol ethoxylates present in the influent incurred microbial attack within 3 hours retention time in the model plant.

The lipid fraction of the sludge from the [1-^{14}C] alkyl ethoxylate experiment had a considerably higher radioactivity than sludge from the ring labeled experiment. This was explained as a consequence of microbial degradation of the alkyl-chain via β-oxidation according to general biochemical pathways, resulting in the production of acetyl units, which represent the elementary precursors for fatty acid biosynthesis.

The relatively high surfactant content in the sludge may result from the comparatively low water solubility of stearyl alcohol + 7 EO. Additionally, the hydrophilic EO-chain of ***alcohol ethoxylates exhibits a slower biodegradation rate than the hydrophobic part of*** the surfactant molecule. The faster biodegradation of the alkyl chain is clearly shown by the fact that the intermediates of the [1-^{14}C] stearyl alcohol ethoxylate biodegradation found in the effluent consisted largely of higher EO-numbered acidic polyethylene glycols which obviously must contain a small ^{14}C labeled moiety. In addition, it is evident that these polyethylene glycol carboxylates can only arise if degradation of the alkyl chain starts at the terminal methyl group. This is in accordance with conclusions drawn by other authors.

The alkyl chain of the fatty alcohol ethoxylate exhibited an ultimate biodegradation of about 75%. The actual extent of degradation may exceed this value for two reasons: (1) the steady state mineralization rate was higher than the balanced value of total $^{14}CO_2$-evolution and (2) an undervaluation results from the ^{14}C-labeling position in connection with the degradation mechanism. The biodegradation begins at the terminal methyl of the alkyl chain, so that in this case, the alkyl carbon in position 1 represents the last carbon being transformed.

From these studies it was concluded that the biodegradation of stearyl alcohol + 7 EO formed no recalcitrant metabolites and would be expected to completely biodegrade under primary sewage treatment, as well as by self-purification processes in surface waters. These findings relate to both aerobic and anaerobic metabolic pathways.

A second study by these authors was published in 1985. Here, Steber and Wierich report that there are two distinct primary degradation mechanisms acting simultaneously in the microbial biocenoses of fatty alcohol ethoxylates: intramolecular scission of the surfactant as well as ω- and β-oxidation of the alkyl chain. In this report, a picture of the microbial pathways that bring about ultimate biodegradation of fatty alcohol ethoxylates in the environment were made. Studies were again conducted in a model continuous flow activated sludge plant similar to that described by the OECD Confirmatory Test.

A fast degradation of the fatty alcohol moiety of the surfactant occurs, beginning with terminal methyl group and slowing down before the radiolabeled C-1 is reached. The terminal oxidation of the alkyl chain (ω-oxidation) and subsequent stepwise removal of C_2 units by β-oxidation is presented as the fatty alcohol chain metabolic process. The resulting products represent the elementary precursors of fatty acid biosynthesis.

In addition to the above work, Speel reports that sodium lauryl sulfate (C_{12}) disappears from water in less than 3 days. The studies with fatty alcohol detergents have generally demonstrated "complete biodegradeability" in three days or less.

Work by other authors has shown that straight-chain alcohols may be a preferred carbon source, or at minimum microorganisms require little conditioning to utilize normal fatty alcohols as a carbon source. Langley (1970) conducted experiments on hexadecanol (C_{16}) and octadecanol (C_{18}) in conjunction with research on the control of water loss from soil in the arid southwest. In conjunction with these efforts, this project was designed to meet two goals: (1) to investigate the behavior of hexadecanol and octadecanol in microbial systems, including the detection, identification and behavior of any intermediate or end products formed as a result of biological transformation; and (2) to correlate the behavior *of long-chain fatty alcohols with studies of lower molecular weight alcohols.*

Three primary analytical techniques were employed to obtain direct and specific measurements of the rate and extent of degradation of hexadecanol and octadecanol by adapted microorganisms: gas chromatography, total organic carbon analysis and recorded oxygen uptake. A settled sewage supernatant was used as the source of microbial organisms which were adapted to the alcohol substrate. Low chain length alcohols (3 and 5 carbon) were used to condition the system and demonstrate its capability to adapt to soluble alcohols as a carbon source. The higher chain alcohols were insoluble in water but formed a film on the water surface. Due to this filming tendency, 1-hexadecanol and 1-octadecanol were tested in a static environment to avoid loss of the compound on flask walls.

1-butanol and 1-pentanol were removed from the solutions within 4 to 6 hours of their introduction. When isopentanol was also present, there appeared to be a selectivity of response which favored the straight chain alcohols. The total organic carbon removal during this phase of experimentation approached first order microbial response with half-lives as short as 2 hours. Similar responses were evoked when cultures were exposed to isobutanol, 1-butanol and 1-pentanol; response to straight chain alcohols was virtually non-selective and the removal of isobutanol was essentially stopped until the straight chain alcohols were removed or converted.

Considerable operational difficulty was experienced in attempts to conduct growth and utilization trials on the higher chain alcohols. Given sufficient time in contact with the adapted microbial species, complete disappearance of 1-hexadecanol and 1-octadecanol as an identifiable molecular species did occur. Experimental difficulties precluded the establishment of an exact half-life, but degradation appeared to be fairly complete within 7 to 10 days. Where these substrates were added in granular, slow release forms, so that disappearance was also slowed, no significant soluble organic accumulation occurred. Where substrate was added in dissolved form (a hexane solution), microbial growth was rapid and there was evidence of soluble organic accumulation above the level of controls. Efforts to extract and identify the organics were unsuccessful, partly due to the presence of hexane as a complicating factor (some adaptation of the microorganisms to hexane may have occurred).

The complications of studying these compounds in both the field and laboratory were discussed. The fact that solvents such as hexane or isopropanol must be used to disperse the compounds in an aquatic system and the ubiquitous presence of carbon make qualification and identification of breakdown products extremely difficult.

In work with fatty alcohols as biomarkers, Simoneit and Mazurek (1982) reported that absolute concentration of the homologs of $<C_{20}$ in aerosol samples were not accurate although quantitative comparisons could be made. They speculated that the presence of shorter chain fatty alcohols were equal to or greater than the concentration of fatty alcohols which are $>C_{20}$. The quantitative comparisons made by Simoniet and Mazurek which include data on chain lengths of 10-35 carbons which are shown in Figure 3. These authors propose that the concentration of $<C_{20}$ fatty alcohols is relatively high in dispersed aerosols, and that the origin of these products is microbial activity resulting **primarily from the breakdown of plant waxes.**

In a living aquatic system, be it aerobic or anaerobic, fatty alcohol breakdown is rapid and complete. Papers reviewed here suggest that the aquatic half-life of shorter-chain fatty alcohols may be a matter of hours, and is likely to be less than 3 to 7 days. Because these types of compounds are a preferred carbon source, they will be rapidly bioassimilated or mineralized to CO_2.

X. SECTION N GUIDELINES, 163-1: LEACHING, ADSORPTION AND DESORPTION

Some of the papers reviewed and the chemical and physical properties of n-alipatic alcohols suggest that these compounds are not mobile in soils. One publication was found which provides data on the movement of n-fatty alcohols in soil. Unfortunately a full copy of this article was not available within the time period for this report's preparation. However, the abstract does provide the following summary information: hydrogen bonding was the primary attraction between the fatty alcohol compound and Wyoming bentonite clay. Binding was rapid and strong, with virtually no lateral or vertical movement detected. Fatty alcohols tendency to bind to soil and stay in place, and the film-forming properties of fatty alcohols of chain length C_{16} and above, are the specific properties which lead to the investigation of these compounds as evaporation inhibitors in soils where water use is critical.

The discovery of fatty alcohols in sedimentary rocks (Hoering, 1969) suggests that movement is limited once the substrate involved is no longer bioactive. Microbial biosynthesis or mineralization may result in the formation of fatty acids or other natural products as well as carbon dioxide. The movement of these compounds may vary; however, they are natural constituents of the soil and are likely to be thoroughly involved in the carbon cycling process.

Again, no FIFRA-guideline type studies are available for the leaching, adsorptive and desorptive properties of C_6 to C_{12} alcohols, but the information presented above, and the general properties of these compounds as described by Hay (1981) suggest that this range of fatty alcohol compounds will not be mobile in the soil.

XI. SECTION N GUIDELINES, 164-1: TERRESTRIAL FIELD DISSIPATION

No articles were discovered which dealt with the dissipation half-life of fatty alcohols in soil. Because these compounds are ubiquitous and constantly cycled through organisms and bioactive soil and water, one would expect that the exposure of soil to fatty alcohol from its use on tobacco would elicit no changes in the metabolic cycles therein. Brengle's (1965) thesis on the behavior of fatty alcohols in soil supports this postulation.

In a later publication, Brengle (1969) conducted field tests of the ability of hexadecanol and octadecanol to inhibit soil moisture loss. Octadecanol was broadcast at 0, 300, 600 or 900 pounds per acre each May for three years. Fatty alcohol, at the rates used in this study, did not retard soil water loss enough to warrant use in a fallow system. The treated area did maintain a protective vegetation cover. Apparently, even these extremely high rates did not affect the productivity of the soil over the three year test period.

The dissipation of fatty alcohols from soils would be expected to follow first order kinetics, with half-lives varying based on the level of microbial activity in the soil. Since most agricultural soils are quite bioactive, and receive fatty alcohols in the form of plant waxes on a regular basis, the dissipation of C_6 through C_{12} n-alcohols can be predicted to be quite rapid. Use rates for tobacco sucker control are several orders of magnitude below those used by Brengle. Brengle used longer chain compounds; however, since oxidation occurs carbon-by-carbon, the shorter chain compounds would be degraded more rapidly, if they are not simply assimilated for use in the fatty acid synthesis pathway.

Several studies in plants dealing with the synthetic pathways used in the production of plant waxes and wax esters give some information on the level of low-chain length fatty alcohols which may be deposited in agricultural soils. That data is not included in the section but is reviewed in the attached bibliography (see: Moreau and Huang, 1979; Wilkinson, 1973; and Wilkinson, 1974). These studies also suggest that the variability of background fatty alcohols in soil will be great, depending upon the specific environmental factors relating to plant growth, nutrition and soil metabolism.

XII. SECTION N GUIDELINES, 165-4: BIOACCUMULATION IN FISH

Fatty alcohols and wax esters are abundant in nature. The fact that one source of the fatty alcohols used in tobacco sucker control agents is plant material is the strongest evidence of their occurrence. Bioaccumulation would not be expected since these compounds are constantly cycled through the carbon pool. Several articles reviewed support this hypothesis.

Wax esters are an abundant source of energy in the marine environment (Place and Roby, 1986). Hydrolysis of wax esters produces fatty alcohols which then are oxidized to or assimilated into fatty acids. Cycling of fatty alcohols begins at the "base" of the food chain. Annelids, crustacea and single celled organisms all assimilate fatty alcohols and acids and are important in affecting the flux of lipids through food chains (Bradshaw, et. al, 1990 and 1990a; Hosotani, et al, 1988).

Obst (1986) reported that the feces of wax-fed birds (Wilson's storm petrel) contain fatty alcohol and fatty acid, again the products of wax hydrolysis. Fish feeding on zooplankton readily digest fatty acids of C_{18} to C_{20} chain length; higher chain lengths are excreted in the feces. The same pattern would be expected for fatty alcohols, except that they are likely to be converted to fatty acids or synthesized into more complex molecules.

In further studies on fish, Cowey and Sargent (1977) followed the distribution and fate of fatty alcohols which resulted from wax ester hydrolysis. These authors reported that fatty alcohols were oxidized to the corresponding acid and thereafter follow pathways of fatty acid metabolism. Some species were reported to have the ability to convert short chain acids into longer chain polyunsaturated acids that have full essential fatty acid activity. This finding would suggest that pathways exist for the rapid assimilation of fatty alcohols.

Similar findings are reported in other types of organisms. Komnick and Bauerfeind (1991) reported that dragonfly larvae hydrolyze wax esters and absorb both the fatty acid and fatty alcohol moieties. These moieties are then used in the synthesis of triglycerides and wax esters. No accumulation of lipid droplets occurred after ingestion of free fatty alcohol alone. Again supporting the rapid assimilation of this class of compounds.

Straight-chain fatty alcohols are considered "building blocks" in fatty acid synthesis and other carbon cycling pathways (Hay, 1981). The existence of these pathways provides for mechanisms which prevent bioaccumulation from occurring. Hence, bioaccumulation in fish, a result of the use of fatty alcohols in tobacco sucker control, definitely would not be expected to occur.

XIII. CONCLUSIONS

Guideline Number 160-5, Chemical Identity: Normal fatty alcohols are considered chemically "inert" and are precursors to fatty acids. Their production and manufacture yields a relatively pure product mixture, depending upon the "cut" desired. The C_6-C_{12} alcohols used in tobacco sucker control agents would be expected to contain no unusual or high levels of impurities.

Guideline Number 161-1, Hydrolysis: Hydrolysis is not a major pathway of degradation for C_6-C_{12} alcohols.

Guideline Number 161-2, Photodegradation in Water: Photolysis of C_6-C_{12} n-alcohols in water would not be expected to occur.

Guideline Number 161-3, Photodegradation in Soil: Photolysis of C_6-C_{12} n-alcohols in soil would not be expected to occur.

Guideline Number 162-1, Aerobic Soil Metabolism: Aerobic soil metabolism is the major degradation pathway for C_6-C_{12} n-alcohols. Breakdown or assimilation by microbial organisms is rapid and complete. Half-lives may be as short as a matter of hours, and would not be expected to exceed 3 to 5 days.

Guideline Number 162-3, Anaerobic Aquatic Metabolism: Anaerobic aquatic metabolism is similar to other microbial metabolism pathways for C_6-C_{12} n-alcohols. End products may differ due to individual organism output, but products will be natural components of the aquatic system. Breakdown or assimilation by microbial organisms is rapid and complete. Half-lives may be as short as a matter of hours, and would not be expected to exceed one day.

Guideline Number 163-1, Leaching/Adsorption/Desorption: C_6-C_{12} fatty alcohols strongly adsorb to soil and would not be expected to move through the soil column. Desorption is expected to be minimal.

Guideline Number 164-1, Terrestrial Field Dissipation: Dissipation of C_6-C_{12} fatty alcohols under field rates and conditions is rapid and complete. Half-lives as short as a matter of hours could be possible. Half-lives would not be expected to exceed 3 to 5 days.

Guideline Number 165-4, Bioaccumulation in Fish: C_6-C_{12} fatty alcohols will not bioaccumulate in fish.

XIV. RAW DATA ARCHIVING

The final copy of this report will be archived in the Quality Assurance files of Compliance Services International. The references collected will be retained or returned to the sponsor and will be made available for further review if that is the desire of the sponsor or regulatory agencies.

XV. CERTIFICATION

The data presented in this report are true and accurate to the best of my knowledge and were taken from peer-reviewed, published articles. Hypotheses presented on the behavior of specific compounds are logical extensions of the information reviewed to date.

Signed: ______________________ Date: __________

XVI. TABLES

Table 1. PHYSICAL PROPERTIES OF FATTY ALCOHOL

IUPAC Name	Common Name	CAS registry No.	Molecular formula	M_r	Hydroxyl Number	mp, °C.	bp, °C (p.kPa)	Density, g/cm^3 (t, °C)	Refractive index (t, °C)
1-Hexanol	caproic alcohol	111-27-3	$C_6H_{14}0$	102.2	548	-52	157	0.819(20)	1.4181(20)
1-Heptanol	cnanthic alcohol	111-70-6	$C_7H_{16}0$	116.2	482	-30	176	0.822(20)	1.4242(20)
1-Octanol	caprylic alcohol	111-87-5	$C_8H_{18}0$	130.2	430	-16	195	0.825(20)	1.4296(20)
1-Nonanol	pelargonic alcohol	143-08-8	$C_9H_{20}0$	144.3	388	-4	213	0.828(20)	1.4338(20)
1-Decanol	capric alcohol	112-30-1	$C_{10}H_{22}0$	158.3	354	7	230	0.829(20)	1.4371(20)
1-Undecanol		112-42-5	$C_{11}H_{24}0$	172.3	326	16	245	0.830(20)	1.4402(20)
1-Dodecanol	lauryl alcohol	112-53-8	$C_{12}H_{26}0$	186.3	300	23	260	0.822(40)	1.4428(20)
1-Tridecanol		112-70-9	$C_{13}H_{28}0$	200.4	280	30	276		
1-Tetradecabol	myristyl alcohol	112-72-1	$C_{14}H_{30}0$	214.4	261	38	172(2.67)	0.823(40)	1.4358(50)
1-Pentadecanol		629-76-5	$C_{15}H_{32}0$	228.4	245	44			1.4408(50)
1-Hexadecanol	cetyl alcohol	36653-82-4	$C_{16}H_{34}0$	242.5	230	49	194(2.67)	0.812(60)	1.4392(60)
1-Heptadecanol	margaryl alcohol	1454-85-9	$C_{17}H_{36}0$	256.5	218	54			
1-Octadecanol	stearyl alcohol	112-92-5	$C_{18}H_{38}0$	207.5	207	58	214(2.67)	0.815(60)	1.4388(60)
1-Nonadecanol		1454-84-8	$C_{19}H_{40}0$	284.5	196	62			1.4328(70)
1-Eicosanol	arachidyl alcohol	629-96-9	$C_{20}H_{42}0$	298.6	187	64	215(1.33)	0.806(70)	
1-Heneicosanol		15594-90-8	$C_{21}H_{44}0$	312.6	179	68			
1-Docosanol	behenyl alcohol	661-19-8	$C_{22}H_{46}0$	326.6	171	71	2411.33	0.807(80)	

Table 2. PRODUCTION PROCESS USED IN FATTY ALCOHOL MANUFACTURE

Name of Process	Raw Material	Predominent Brief Description	Chain Lengths
Hydrolysis of Wax Esters	Sperm Oil	Oil is heated with concentrated sodium hydroxide at about 300°C	C_{16}-C_{20}
Reduction of Wax Esters with Sodium	Sperm Oil	Molten-Sodium is dispensed in an inert solvent and then carefully dried ester and alcohol are added. When the reaction is complete, the alkoxides are split by stirring in water, and the alcohols are washed and distilled	Unsaturated especoleyl alcohol
Hydrogenation of Natural Raw Materials (Proctor & Gamble)(Henkel)	Coconut or Palm Kernel Oil Palm Oil, Soybean oil, tallow Rapeseed oil	Impurties removed in a cleaning stage. Refined Triglycerides are hydrolyzed to yield fatty acids or trans-esterified with lower alcohols to yield fatty acid esters. Hydrogenation is by suspension, gas-phase or tricle-bed.	C_6-C_{18} C_{16} - C_{18} C_{20}-C_{22}
Ziegler Alcohol Process - Alfol (Vista)	Petrochemical feedstocks	Hydrogenation, ethylation, growth reaction, oxidation, hydrolysis, fractionation.	C_2-C_{26}
Ziegler Alcohol Process - Epal (Ethyl Corp)	Petrochemical feedstocks	As above, but growth reaction is limited.	C_6-C_{20}
Oxo Process (hydroformulation)	Petrochemical feedstocks	Reaction of olefins with an H_2-CO gas mixture in their presence of suitable catalyts.	n-butanol and 2-ethylhexanol
Hydrogenation of Fatty Acids	Oxidized Paraffinic Hydrocarbons	Mixture of parafins is oxidized above 100°C in the presence of manganese catalyts.	Linear, primary alcohols with many by products C_{10}-C_{20}
Bashkirov Oxidation	Parafins	Oxidation in the presence of boric acid at 160°C	Secondary alcohols
Other Processes	X-Olefins	Reaction with hydroperoxides in the presence of transition metal catalyts.	Isobutanol, C_{30}-C_{50}

Table 4. PROPERTIES OF SOME STRAIGHT-CHAIN ALCOHOLS					
Name	Formula	Molecular Weight	m.p. °C	b.p. °C	Water solubility (g 100 ml^{-1})
Methanol	CH_3OH	32	-94	65	*
Ethanol	C_2H_5OH	46	-117	70	*
1-propanol	C_3H_7OH	60	-127	97	*
1-butanol	C_4H_9OH	74	-90	117	8·0
1-pentanol	$C_5H_{11}OH$	88	-79	137	2·2
1-hexanol	$C_6H_{13}OH$	102	-47	158	0·6
1-heptanol	$C_7H_{15}OH$	116	-34	176	0·1
1-octanol	$C_8H_{17}OH$	130	-17	195	0·04
1-decanol	$C_{10}H_{21}OH$	158	7	229	0·004

*Soluble in all proportions of water to alcohol.

XVII. FIGURES

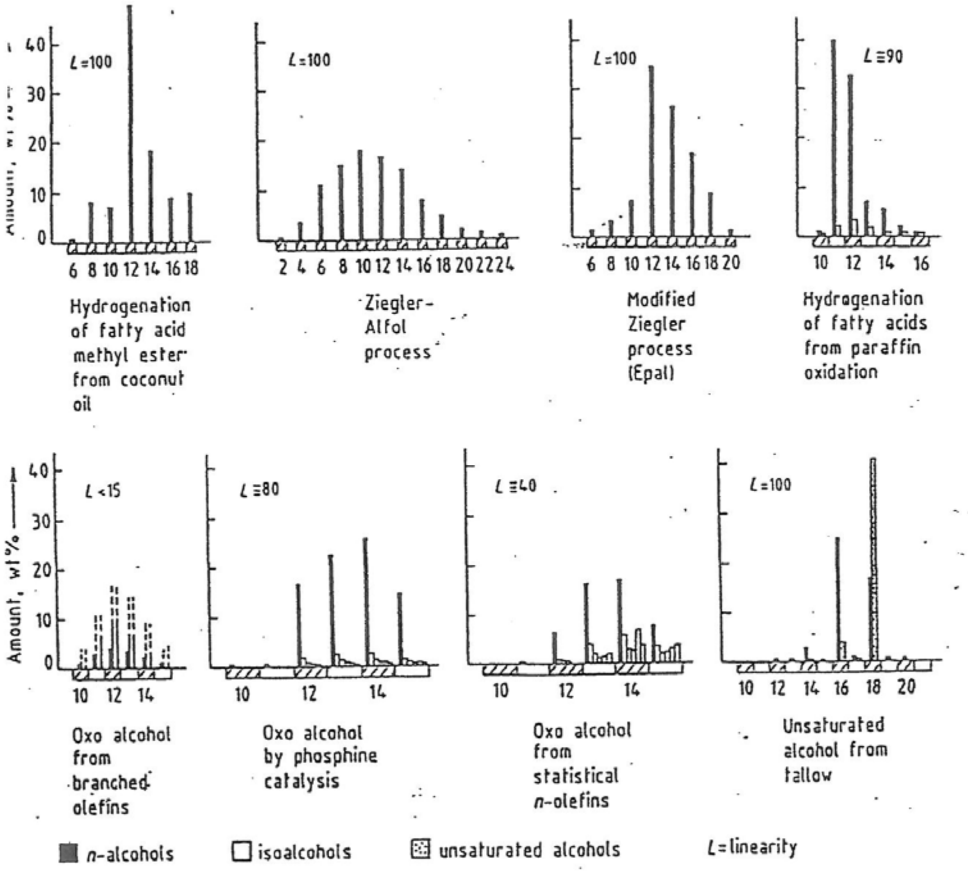
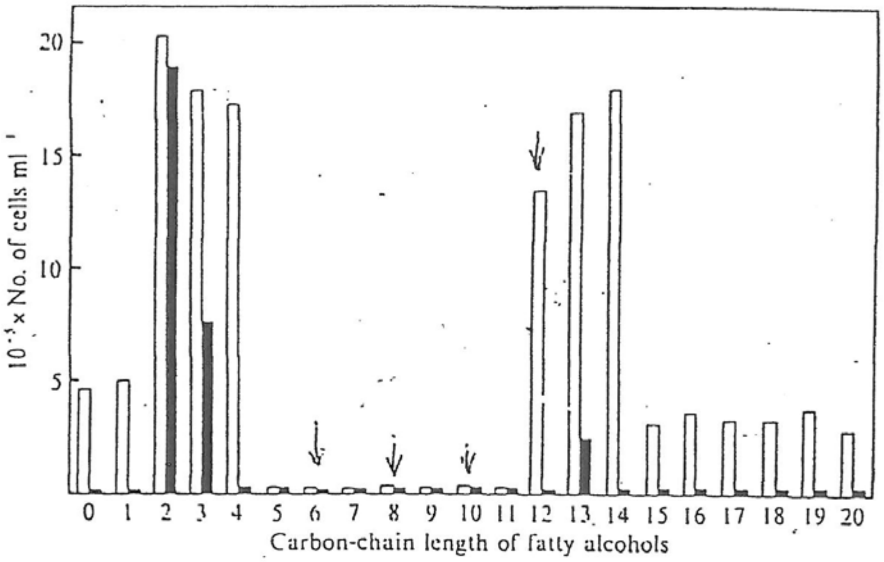


Figure1 . Typical fatty alcohol compositions obtained by different processes



Photoautotrophically grown cells are transferred to culture media containing individual fatty alcohol and cultivated for 14d with or without illumination. Initial cell number was 0.9 x 10^{-1}. Open and closed bars represent growth of Euglina with and without illumination respectively. A carbon chain length of 0 indicates photoautotrophic growth.

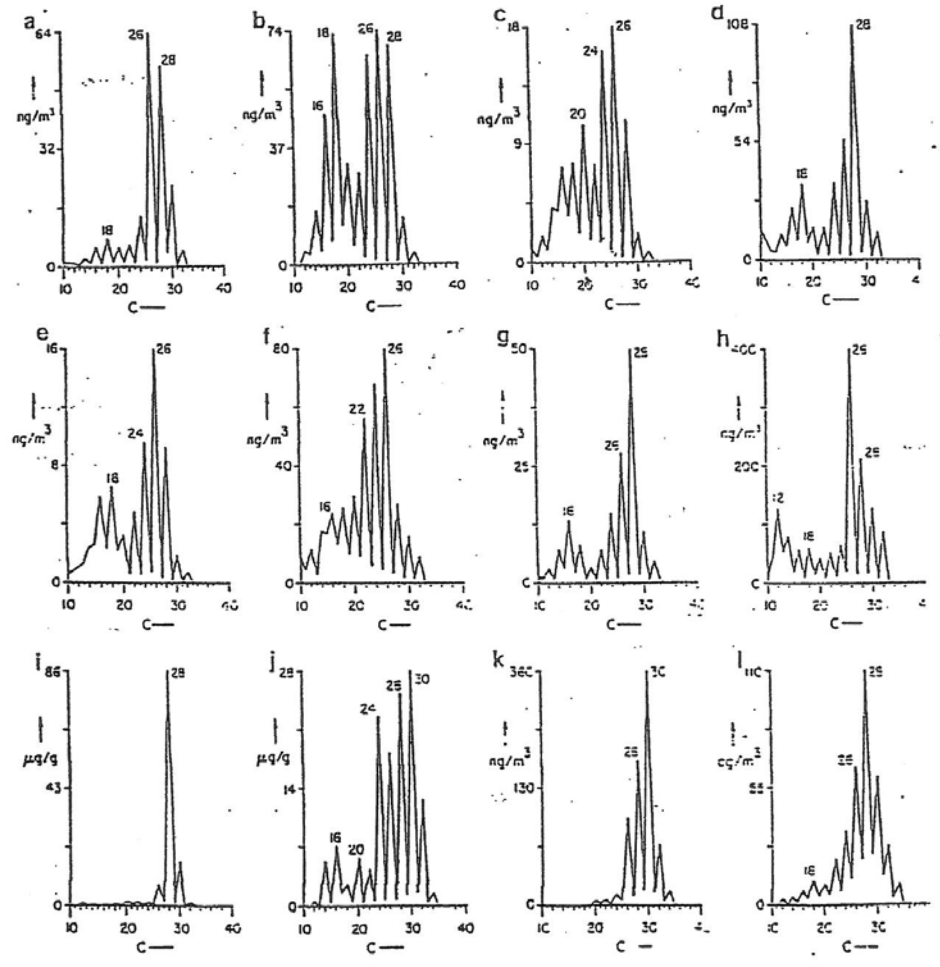


Fig. 3 . Distribution diagrams for the *n*-fatty alcohols: (a) Battle Creek Meadow Ranch (sample 6); (b) Sugarpine Point State Park, night, summer (sample 1); (c) Sierra Ski Ranch (sample 5); (d) Sugarpine Point State Park, winter (sample 3); (e) D and D Ranch, summer (sample 8); (f) Corvallis, forest (sample 14); (g) Canoga Park, Santa Ana conditions (sample 16); (h) Pasadena (sample 17); (i) Composited grass, wax (sample 20); (j) Composited conifers, wax (sample 21); (k) Harmattan aerosol, Jos, Nigeria (Cox *et al.*, 1982); (l) Atlantic Ocean, DC 4 (Simoneit, 1977a).

XVIII. ANNOTATED BIBLIOGRAPHY

Abstracts only (-)
Article reviewed (✓*)
Referenced by author
and referenced information
is
presented (*)

✓*Ambles, A., J. C. Jacquesy, P. Jambu, et al. 1991. Polar lipid fraction in soil - a kerogen-like matter. Organic Geochemistry 17(3):341-349.

> "Soil lipids include a great number of neutral or acid components (hydrocarbons, esters, ketones, fatty alcohols and acids) which can be easily studied ("simple lipids") and an unknown, barely soluble, fraction called "polar fraction" or "complex lipids"."
>
> In reviewing the work of others, conducted to identify the relationship of simple lipids to complex lipids in soils, Ambles observed that the experimental results "suggested that the soil polar fraction may correspond to a polar matrix (a biopolymer) which can "react" with simple lipids, the process of incorporation of simple lipids being reversible in biologically-active soils."
>
> Ambles selected two hydromorphic soils from the western part of France for his studies. He compared the simple lipids in the soil to the breakdown products of the "polar fraction". The *n*-alkanes displayed a relatively regular distribution ranging from C_{16} to C_{36}. In further extraction processes, primarily even-carbon number, straight chain alkanols (maximum chain length C_{22}) were found in both soils. His work also showed that the distribution of simple lipids was similar to the products derived from the breakdown of the polar fraction of the soil, suggesting that his initial premise may be valid, and that the polar fraction of the soil is a "sink" for the fatty alcohols and lipids introduced into the soil from plant fractions and microbial activity.

*Aubertin, G.M., G. W. Gorsline. 1964. Effect of fatty alcohol on evaporation and transpiration. Agron. J56:50-52.

*Barras, D. R., & B. A. Stone. 1969. Carbohydrate composition and metabolism in Euglena. In **The Biology of Euglena**, Vol. 2, pp. 149-191. Edited by D. E. Buetow. NY:Academic Press.

Bradshaw, S. A., S. C. M. O'Hara, E. D. S. Corner, et al. 1990. Changes in lipids during simulated herbivorous feeding by the marine crustacean *Neomysis integer*. Journal of the Marine Biological Association of the United Kingdom. 70(1):225-244.

> The results of these investigations indicate that crustaceans such as that tested here would have a profound effect on fatty acid and alcohol fractions in material that passes though the pelagic food chain; feeding activity of these organisms may determine certain aspects of the sedimentary lipid distributions.

Bradshaw, S. A., S. C. M. O'Hara, E. D. S. Corner. 1990. Dietary lipid changes during herbivory and coprophagy by the marine invertebrate *Nereis diversicolor*. Journal of the Marine Biological Association of the United Kingdom. 70(4):771-788.

> Herbivorous and particularly coprophagous feeding by the annelid worm, *Nereis diversicolor* leads to relatively high abundances of "bacterial" odd carbon-number normal and branched chain fatty acids and these organisms are important in affecting the flux of lipids through marine food chains.

Brengle, K. G. 1965. The behavior of fatty alcohol applied to soils. Dissertation, Michigan State University (reported in Dissertation Abstracts International, 26(2):615.

Fatty alcohol absorption by Wyoming ventonite was studied by x-ray diffraction, differential thermal analysis, infra-red absorption and angle of wetting. Hydrogen bonding was assumed to be the primary attraction between fatty alcohol and ventonite. Fatty alcohols were found to be active in reducing water movement in soil at extremely high rates (see Brengle, 1969). This research was conducted with a special interest in fatty alcohols as evaporation control agents. Vertical and lateral movement of fatty alcohol in the soil was practically non-existent. the lack of lateral movement suggests that compressed monofilms are not formed at the air-water interface in the soil.

*Brengle, K. G., H. O. Mann. 1969. Effect of fatty alcohol on change in soil water during the summer fallow period. Journal of Soil and Water Conservation. 24(1):25-26.

Hexadecanol and octadecanol were used in an experiment assessing the capability of these compounds to inhibit soil moisture loss. Octadecanol was broadcast at 0, 300, 600 or 900 pounds per acre each May for three years. Fatty alcohol, at the rates used in this study, did not retard soil water loss enough to warrant use in a fallow system. The treated area did maintain a protective vegetation cover.

*Broddin, G. W. Cautreels & D. van Cauwenberghe. 1980. On the aliphatic and polyaromatic hydrocarbon levels in urban and background aerosols from Belgium and the Netherlands. Atmospheric Environment 14:895-910.

✓*Brown, H. 1983. The stability of esters to hydrolysis. Cosmetics and Toiletries. 98(12):56-58.

Six fatty alcohol esters were selected for hydrolysis studies: C_{12-15} alcohols benzoate, isopropyl myristate, isopropyl palmitate, lauryl lactate, dioctyl adipate and isononyl isononate. Lauryl lactate was included since it hydrolyzes readily and would be a good comparison standard reference. The hydrolysis methodology utilized 95% ethanol solutions and pH levels of 2, 3, and 12. Ten percent ester solutions were prepared and subjected to 3 hour reflux and oven storage (47°C for 30 days). Hydrolysis was measured by titration. The method utilized for alkaline hydrolysis was inadequate and no results were obtained. Under acid conditions, laurel lactate had the greatest degree of hydrolysis at both 3 hour reflux and 30 day storage intervals. While the behavior of the ester is determined in these studies, no specific data is provided on the alcohols or their stability in this system.

Buning-Pfaue, H., H. J. Rehm. 1972. Production of aldehyde from "batch" fermentation by *Pseudomonas aeruginosa* growing on decanol. Arch. Mikrobiol. 86(3):231-40.

A *Pseudomonas* species was able to produce fermentation products based on the use of decanol as a sole source of nutrients. This suggests that soil microorganisms readily incorporate fatty alcohols into their nutrient assimilation cycles.

*Cook, K. A. 1979. Degradation of non-ionic surfactant Dobanol 45-7 by activated sludge. Water Res. 13:259-266.

Cowey, C. B., J. R. Sargent. 1977. Lipid nutrition in fish. Comparative Biochemistry and Physiology B: Comparative Biochemistry. 57(4):269-274.

Currie, B. R., R. B. Johns. 1989. An organic geochemical analysis of terrestrial biomarkers in a transect of the Great Barrier Reef Lagoon, Queensland, Australia. Australian Journal of Marine and Freshwater Research. 40(3):275-284.

Fatty alcohols, as well as certain other compounds are being used as "biomarkers" to determine the deposition and source of marine sediments. Fatty alcohols are deposited not only from terrestrial sources but also from planktonic sources and thus are not well correlated with distance-from-land.

> Fatty alcohols resulting from wax ester hydrolysis are oxidized to the corresponding acid and thereafter follow pathways of fatty acid metabolism. Some species have the ability to convert short chain acids into longer chain polyunsaturated acids that have full essential fatty acid activity.

*Finnerty, W. R. & M. E. Singer. 1984. A microbial biosurfactant - physiology, biochemistry and applications. Dev. Ind. Microbiol 25:31-40.

Garrett, W. D. 1964. The organic chemical composition of the ocean surface. Naval Research Laboratory (Washington) Report No. NRL-6201. NTIS No. AD-610 396.

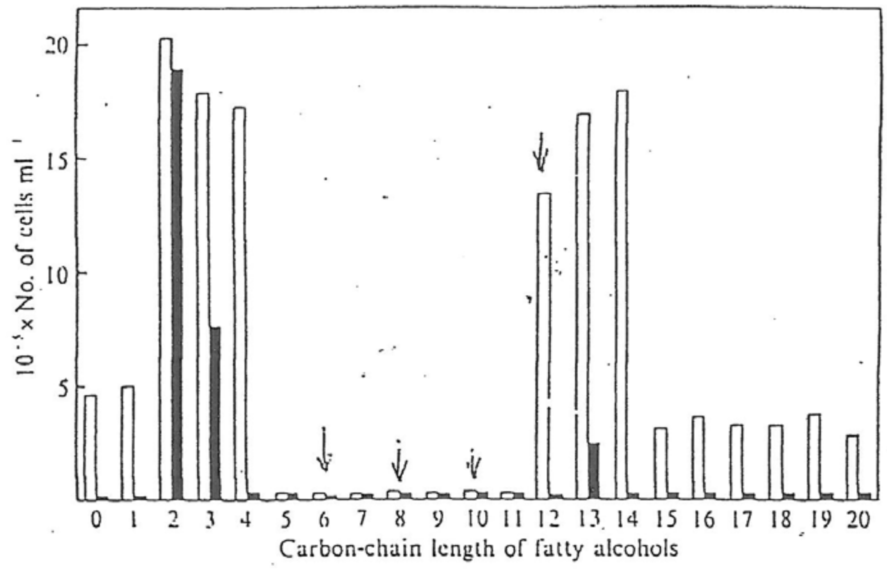
> The major water-insoluble organic constituents of the sea are fatty esters, free fatty acids, fatty alcohols and hydrocarbons. The distribution of the various fatty acids and alcohols varies according to the meteorological and oceanographic conditions prevalent at a particular location. The high molecular weight and less-water soluble fatty alcohols are the most surface active (likely to be found absorbed to the surface) while the more water soluble (less surface active) compounds are excluded from the surface by competition with these compounds.

*Gentner, W. A. 1966. The influence of EPTC on external foliage wax deposition. Weeds 14:27-31.

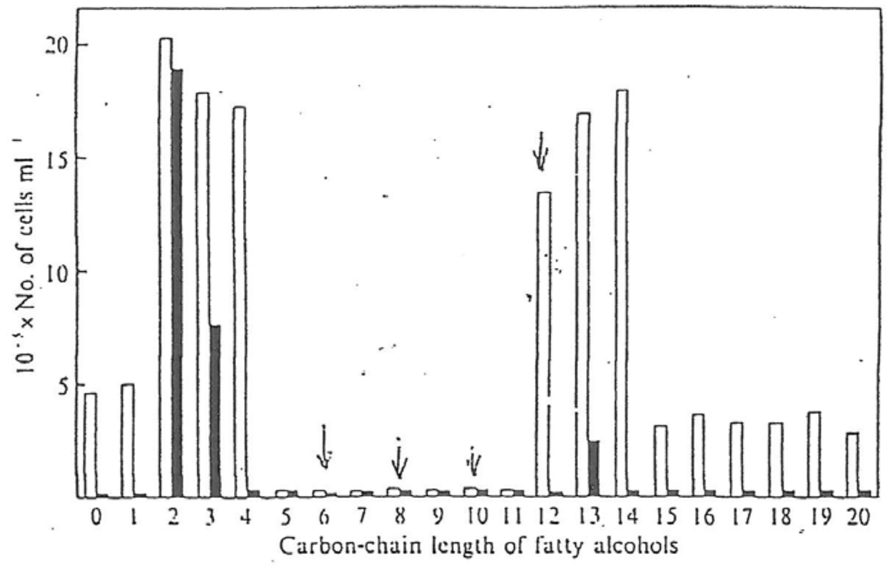
Gerhold, R. M. & G. W. Malaney. 1966. Structural Determinants in the Oxidation of Aliphatic Compounds by Activated Sludge. Journal Water Pollution Cont. Fed. 38(4):562-79.

✓*Hosotani, K., T. Ohkochi, H. Inui, et al. 1988. Photoassimilation of fatty acids, fatty alcohols and sugars by *Euglen* *gracilis* Z. Journal of General Microbiology. 134(1):61-66.

> The assimilation of fatty alcohols and other carbon sources by *Euglena gracilis* Z. was investigated by studying th growth of the organism and its photoassimilation of these compounds. This investigation demonstrates the effect of ligh on the growth of *Euglena* and compares the mechanisms of their photoassimilation.
>
> *E. gracilis* Z and its streptomycin-bleached mutant from established stock cultures were exposed to growth medi containing 0.2% fatty alcohols (carbon chain lengths of 1 to 20). Cell numbers were determined by hemacytomete counts. Where investigation included the use of 1-tetradecanol (myristyl alcohol), extraction was by chloroform, wit determination by gas-liquid chromatography.
>
> *E. gracilis* growth varied depending upon the chain length of the alcohols included in the culture medium. Ethanol wa the best carbon source in both light and dark. Propanol, butanol, 1-dodecanol, 1-tridecanol, and 1-tertadecanol als supported considerable growth under illumination. Assimilation of butanol, dodecanol and tetradecanol for growt strictly depended upon light. The fatty alcohols C_5-C_{11} inhibited growth, while methanol and the alcohols C_{15}-C_{20} did n support growth.



Photoautotrophically grown cells are transferred to culture media containing individual fatty alcohol and cultivated for 14d with or without illumination. Initial cell number was 0.9×10^{-1}. Open and closed bars represent growth of Euglina with and without illumination respectively. A carbon chain length of 0 indicates photoautotrophic growth.



Photoautotrophically grown cells are transferred to culture media containing individual fatty alcohol and cultivated for 14d with or without illumination. Initial cell number was 0.9 x 10^{-1}. Open and closed bars represent growth of Euglina with and without illumination respectively. A carbon chain length of 0 indicates photoautotrophic growth.

The results of the photoassimilation experiments show that photosynthetic energy is not completely necessary for the photoassimilation of the alcohol. The blue light receptor may take part in the photoassimilation of myristyl alcohol; photosynthesis also appears to have some relation to photoassimilation since the occurrence of photosynthesis during the soldering caused a higher cell yield.

✓*Hoering, T. C. 1969. Fatty alcohols in sedimentary rocks. Yearbook of the Carnegie Institute of Washington. 67:202-203.

". . . Mild thermal treatment of unextracted recent sediment produced a good yield of the normal alkanes n-$C_{22}H_{46}$ and n-$C_{24}H_{50}$ and that under the same conditions recent sediment will reduce fatty alcohol to an alkane. These considerations suggest that fatty alcohols in the form of wax esters may be present in sedimentary rocks. Plant waxes are esters of fatty acids and fatty alcohols . . . where [carbon chain lengths] typically run from 12 to 30." [plus two for the initial and terminal carbons] . . . Fatty alcohols, presumably present in the form of wax esters, make a small but significant contribution to the inventory of normal alkyl groups found in sedimentary rocks."

*Ichikawa, Y., Y. Kitamoto & N. Hosoi. 1978. Degradation of polyethylene glycol ethers by a Pseudomonad isolated from activated sludge. J. Ferm. Techanol. 56:403-409.

*Ioneda, T. 1984. Lips of Actinomycetes: Their structure and biosynthesis In Biological, Biochemical and Biomedical Aspects of Actinomycetes. Ed. by L. Ortiz-Ortiz, L. F. Bojalil and Y. Yakoleff. Acad. Press. NY pp. 239-49.

*Jambu, P., G. Coulibaly, P. Bilong et al. 1983. Influence of lipids on physical properties of soil. Studies About Humus Humas & Planta. VIII 1:46-50.

*Kolattukudy, P.E. 1968. Tests whether a head to head condensation mechanism occurs in the biosynthesis of n-hentriacontaine, the paraffin of spinach and pea leaves. Plant Physiol. 43:1466-1470.

*Kolattukudy, P.E. & T. J. Liu. 1970. Direct evidence for biosynthetic relationships among hydrocarbons, secondary alcohols and kitones in *Brassica oleracea*. Biochem. Biophys. Res. Commun. 41:1369-1374.

Komnick, H., R. Bauerfeind. 1991. Intestinal absorption of defined lipids by the larval dragonfly *Aeshna cyanea* (Insecta, Odonata) - wax esters and fatty alcohols. Journal of Insect Physiology. 37(3):179*f*.

Dragonfly larvae hydrolyse wax esters and absorb both the fatty acid and fatty alcohol moieties. These components are then used in the synthesis of triglycerides and wax ester. No accumulation of lipid droplets occurs after ingestion of free fatty alcohol alone. Wax ester is a natural constituent of the larval cuticle of this species.

✓*Langley, W. D. Intermediate products in the bacterial decomposition of hexadecanol and octadecanol. Technical Report # TR-29; W70-09829; OWRR-A-012-TEX(1). Texas A&M University Water Resources Institute. NTIS Accession #PB-194-237.

In the arid climate of the southwest, control of water loss by the use of monolayer films was investigated. In conjunction with these efforts, this project was designed to meet two goals: (1) to investigate the behavior of hexadecanol and octadecanol in microbial systems, including the detection, identification and behavior of any intermediate or end products formed as a result of biological transformation; and (2) to correlate the behavior of long-chain fatty alcohols with studies of lower molecular weight alcohols.

Three primary analytical techniques were employed to obtain direct and specific measure of the rate and extent of degradation of hexadecanol and octadecanol by adapted microorganisms: gas chromatography, total organic carbon analysis and recorded oxygen uptake. A settled sewage supernatant was used as the source of microbial organisms which were adapted to the alcohol substrate. Low chain length alcohols (3 and 5 carbon) were used to condition the system and demonstrate its capability to adapt to soluble alcohols as a carbon source. The higher chain alcohols were insoluble in water but formed a film on the water surface. Due to this filming tendency, 1-hexadecanol and 1-octadecanol were tested in a static environment to avoid loss of the compound on flask walls.

1-butanol and 1-pentanol were removed from the solutions within 4 to 6 hours of their introduction. When isopentanol was also present, there appeared to be a selectivity of response which favored the straight chain alcohols. The total organic carbon removal during this phase of experimentation approached first order microbial response with half-lives as short as 2 hours. Similar responses were evoked when cultures were exposed to isobutanol, 1-butanol and 1-pentanol; response to straight chain alcohols was virtually non-selective and the removal of isobutanol was essentially stopped until the straight chain alcohols were removed or converted.

Considerable operational difficulty was experienced in attempts to conduct growth and utilization trials on the higher chain alcohols. Given sufficient time in contact with the adapted microbial species, complete disappearance of 1-hexadecanol and 1-octadecanol as an identifiable molecular species will occur. Experimental difficulties precluded the establishment of an exact half-life, but degradation appeared to be fairly complete within 7 to 10 days. Where these substrates were added in granular, slow release forms, so that disappearance was also slowed, no significant soluble organic accumulation occurred. Where substrate was added in dissolved form (a hexane solution), microbial growth was rapid and there was evidence of soluble organic accumulation above the level of controls. Efforts to extract and identify the organs were unsuccessful, partly due to the presence of hexane as a complicating factor (some adaptation to hexane may have occurred).

The complications of studying these compounds in both the field and laboratory were discussed. The fact that solvents such as hexane or isopropanol must be used to disperse the compounds in a aquatic system and the ubiquitous presence of carbon make qualification and identification of breakdown products extremely difficult.

*Larson, R.J. & L.M. Games. 1981. Biodegradation of linear alcohol ethoxylates in natural TRANSLATED BY The British Library Document Supply Center. Boston Spa, Wetherby, West Yorkshire LS23 7BQ, United Kingdom. BLDSC 5828.4 (M-52051).

Lindstedt, M., S. Allenmark, R. A. Thompson and L. Edebo. 1990. Antimicrobial activity of betaine esters quaternary ammonium amphiphiles which spontaneously hydrolyze into non-toxic components. Antimicrobial Agents and Chemotherapy. 34(10):1949-1954.

*Lorenzen, G.A. and W. W. Meinke. 1968. A feasibility study on the utilization of monomolecular films for mosquito abatement. Mosquito News 28:230-232.

*Mann, H. Biological effects of fatty alcohols on freshwater animals. Internationale Revue der Gesamten Hydrobiologie. 56:599-607. TRANSLATED BY The British Library Document Supply Center. Boston Spa, Wetherby, West Yorkshire LS23 7BQ, United Kingdom. BLDSC 5828.4 (M-52051).

*Miller, S. and Q.D. Maddock. 1970. Ovicidal effect of selected compounds on the eggs of Anopheles albimanus. Journal of Economic Entomology. 63:1151-1154.

Moreau, R. A., A. H. C. Huang. 1979. Oxidation of fatty alcohol in the cotyledons of jojoba seedlings. Archives of Biochemistry and Biophysics. 194(2):422-430.

During the germination of jojoba (*Simmondsia chinensis*) seeds, fatty alcohols are formed from the hydrolysis of stored wax esters. The cotyledon extract has the ability to convert fatty alcohols to fatty aldehydes in the presence of molecular

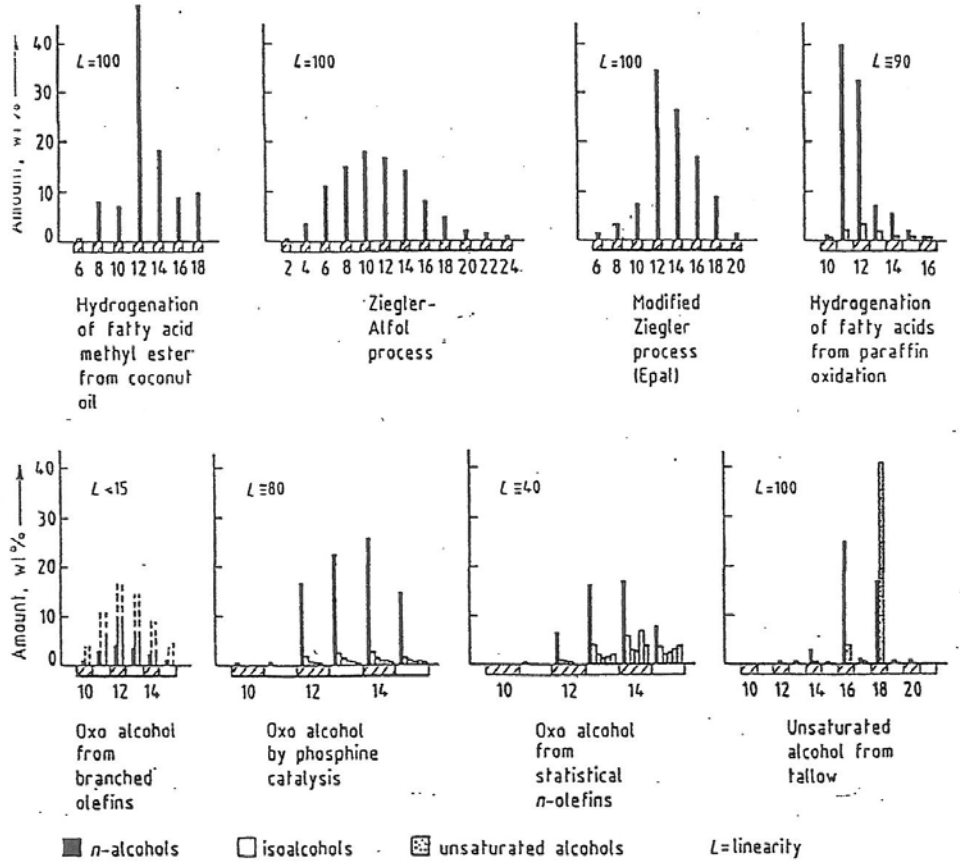
O_2 and subsequently to fatty acids when NAD+ is added. The whole fatty alcohol oxidation system is capable of oxidizing monosaturated fatty alcohols which are the physiological substrates in jojoba cotyledons.

✓*Noweck, K., H. Ridder. 1987. Fatty alcohols. In Ullman's Encyclopedia of Industrial Chemistry, 5th ed. A10(4): 277-296. VCH Publishers Inc., New York.

Fatty alcohols are aliphatic alcohols with chain lengths between C_6 and C_{22}. They are predominantly straight-chain and monohydric, and can be saturated or have one or more double bonds. Alcohols with a chain length above C_{22} are referred to as wax alcohols. The character of fatty alcohols is determined by the manufacturing process and the raw materials used. Natural products, such as fats, oils and waxes, and the Ziegler alcohol process give straight-chain, primary, even-numbered alcohols. Other types of dimerization and oxidation processes give branched chain or secondary alcohols of various characteristics.

"Natural fatty alcohols" are derived from renewable resources, such as fats, oils and waxes of plant or animal origin. "Synthetic fatty alcohols" are produced from petrochemicals such as olefins and paraffins. Up until 1930, the manufacture of fatty alcohols was based almost exclusively on the splitting of sperm oil. The invention of high-pressure hydrogenation was developed at that time and allowed the use of new raw materials. In 1985, the world nameplate production capacity of fatty alcohols was estimated at 1.3×10^6 t/a, of which about 60% was based on petrochemicals. Fatty alcohols and their derivatives are used in synthetics, surfactants, oil additives and cosmetics and have many specialty uses, such as sucker control agents in tobacco.

Physical Properties: Saturated fatty alcohols up to dodecanol (12 carbons) are clear, colorless liquids with a lower specific density than water. The lower members of the series have a characteristic odor. The physical properties of straight-chain, primary alcohols are summarized in the table below.



Hydrogenation of fatty acid methyl ester from coconut oil

Ziegler-Alfol process

Modified Ziegler process (Epal)

Hydrogenation of fatty acids from paraffin oxidation

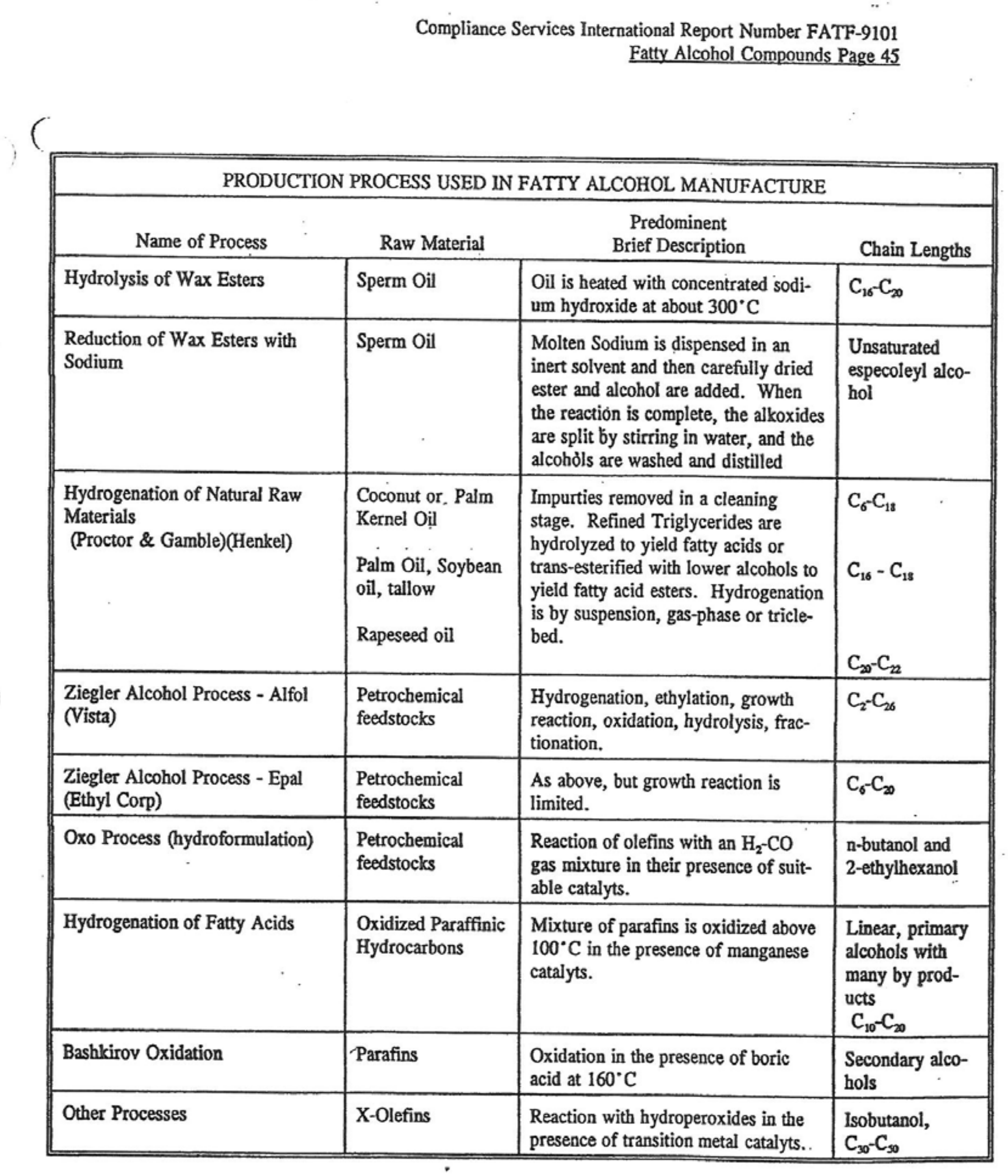
Oxo alcohol from branched olefins

Oxo alcohol by phosphine catalysis

Oxo alcohol from statistical n-olefins

Unsaturated alcohol from tallow

Figure 1 . Typical fatty alcohol compositions obtained by different processes



PRODUCTION PROCESS USED IN FATTY ALCOHOL MANUFACTURE

Name of Process	Raw Material	Predominent Brief Description	Chain Lengths
Hydrolysis of Wax Esters	Sperm Oil	Oil is heated with concentrated sodium hydroxide at about 300°C	C_{16}-C_{20}
Reduction of Wax Esters with Sodium	Sperm Oil	Molten Sodium is dispensed in an inert solvent and then carefully dried ester and alcohol are added. When the reaction is complete, the alkoxides are split by stirring in water, and the alcohols are washed and distilled	Unsaturated especoleyl alcohol
Hydrogenation of Natural Raw Materials (Proctor & Gamble)(Henkel)	Coconut or Palm Kernel Oil Palm Oil, Soybean oil, tallow Rapeseed oil	Impurties removed in a cleaning stage. Refined Triglycerides are hydrolyzed to yield fatty acids or trans-esterified with lower alcohols to yield fatty acid esters. Hydrogenation is by suspension, gas-phase or tricle-bed.	C_6-C_{18} C_{16} - C_{18} C_{20}-C_{22}
Ziegler Alcohol Process - Alfol (Vista)	Petrochemical feedstocks	Hydrogenation, ethylation, growth reaction, oxidation, hydrolysis, fractionation.	C_2-C_{26}
Ziegler Alcohol Process - Epal (Ethyl Corp)	Petrochemical feedstocks	As above, but growth reaction is limited.	C_6-C_{20}
Oxo Process (hydroformulation)	Petrochemical feedstocks	Reaction of olefins with an H_2-CO gas mixture in their presence of suitable catalyts.	n-butanol and 2-ethylhexanol
Hydrogenation of Fatty Acids	Oxidized Paraffinic Hydrocarbons	Mixture of parafins is oxidized above 100°C in the presence of manganese catalyts.	Linear, primary alcohols with many by products C_{10}-C_{20}
Bashkirov Oxidation	Parafins	Oxidation in the presence of boric acid at 160°C	Secondary alcohols
Other Processes	X-Olefins	Reaction with hydroperoxides in the presence of transition metal catalyts.	Isobutanol, C_{30}-C_{50}

Table 1. PHYSICAL PROPERTIES OF FATTY ALCOHOLS

Table 1. PHYSICAL PROPERTIES OF FATTY ALCOHOL

1UPAC Name	Common Name	CAS registry No.	Molecular formula	M_1	Hydroxyl Number	mp, °C	bp, °C (p.kPa)	Density, g/cm³ (t, °C)	Refractive index (t, °C)
1-Hexanol	caproic alcohol	111-27-3	$C_6H_{14}0$	102.2	548	-52	157	0.819(20)	1.4181(20)
1-Heptanol	enanthic alcohol	111-70-6	$C_7H_{16}0$	116.2	482	-30	176	0.822(20)	1.4242(20)
1-Octanol	caprylic alcohol	111-87-5	$C_8H_{18}0$	130.2	430	-16	195	0.825(20)	1.4296(20)
1-Nonanol	pelargonic alcohol	143-08-8	$C_9H_{20}0$	144.3	388	-4	213	0.828(20)	1.4338(20)
1-Decanol	capric alcohol	112-30-1	$C_{10}H_{22}0$	158.3	354	7	230	0.829(20)	1.4371(20)
1-Undecanol		112-42-5	$C_{11}H_{24}0$	172.3	326	16	245	0.830(20)	1.4402(20)
1-Dodecanol	lauryl alcohol	112-53-8	$C_{12}H_{26}0$	186.3	300	23	260	0.822(40)	1.4428(20)
1-Tridecanol		112-70-9	$C_{13}H_{28}0$	200.4	280	30	276		
1-Tetradecabol	myristyl alcohol	112-72-1	$C_{14}H_{30}0$	214.4	261	38	172(2.67)	0.823(40)	1.4358(50)
1-Pentadecanol		629-76-5	$C_{15}H_{32}0$	228.4	245	44			1.4408(50)
1-Hexadecanol	cetyl alcohol	36653-82-4	$C_{16}H_{34}0$	242.5	230	49	194(2.67)	0.812(60)	1.4392(60)
1-Heptadecanol	margaryl alcohol	1454-85-9	$C_{17}H_{36}0$	256.5	218	54			
1-Octadecanol	stearyl alcohol	112-92-5	$C_{18}H_{38}0$	207.5	207	58	214(2.67)	0.815(60)	1.4388(60)
1-Nonadecanol		1454-84-8	$C_{19}H_{40}0$	284.5	196	62			1.4328(70)
1-Eicosanol	arachidyl alcohol	629-96-9	$C_{20}H_{42}0$	298.6	187	64	215(1.33)	0.806(70)	
1-Heneicosanol		15594-90-8	$C_{21}H_{44}0$	312.6	179	68			
1-Docosanol	behenyl alcohol	661-19-8	$C_{22}H_{46}0$	326.6	171	71	2411.33	0.807(80)	

Uses: Fatty alcohols are mainly used as intermediates. Surfactants account for 70-75% of fatty alcohol production. The most important groups of surfactants are alkyl polyglycol ethers, alkyl sulfates and alkyl polyglycol ether sulfates. On a much smaller volume, fatty alcohols are used in cosmetic creams, lotions and industrial emulsions.

Analytical Methods: Analytical methods for quality control purposes are defined by DIN [101], ASTM [102] and the Deutsche Gesellschaft für Fettwissenschaft (DGF) [103]. the parameters measured typically include (where appropriate of the compound under production): composition (by gas chromatography), hydrocarbon content, color, refractive index, density, viscosity, solidification point, boiling range, flash point, ignition temperature, hydroxyl number, carbonyl number, peroxide number, iodine number, acid number, saponification number and water content. The sources of fatty alcohols used for tobacco desuckering include those produced from coconut and other natural oils and those produced from petroleums compounds by the Ziegler Process. Coconut alcohols produce very few impurity peaks and contain less that 0.1% n-tridecanol and varying amounts of n-alkanes. Ziegler alcohols are primary, straight chain alcohols with an even carbon number. Gas chromatography shows up to 1.0% impurities, consisting of numerous even-numbered, isomeric fatty alcohols.

*Neufahrt, A., K. Lötzsch & D. Gantz. 1982. Biodegradability of ^{14}C-labeled ethoxylated fatty alcohols. Tenside Detergents 19:264-268.

*Nooi, J.R., M.C. Testa & S. Willemse. 1970. Biodegradation mechanisms of fatty alcohol non-ionics. Tenside Detergents. 7:61-65.

*Olsen, S.R., F. S. Watanabe, F. E. Clark Et al. 1964. Effect of hexadecanol on evaporation of water from soil. Soil Sci. 97:13-18.

Obst, B. S. 1986. 1986. Wax digestion in Wilson's storm petrel *Oceanites oceanicus*. Wilson Bulletin. 98(2):189-195.

Wax esters are an abundant source of energy in the marine environment. Hydrolysis of the wax ester produces fatty alcohols which are then oxidized to or assimilated into fatty acids.

*Patterson, S.J., C.C. Scott & K.R.E. Tucker. 1970. Nonionic detergent degradation. III. Initial mechanism of the degradation. J. Am. Oil Chem. Soc. 47:37-41.

Peltzer, E. T., R. B. Gagosian. Sampling and quantitation of lipids in aerosols from the remote marine atmosphere. Anal. Chim. Acta. 198:125-144.

Air and rain samples were collected to demonstrate the efficiency of an analytical method for five classes of naturally occurring lipids, one of which was fatty alcohols of C13 to C36 chain length.

Place, A. R., D. D. Roby. 1986. Assimilation and deposition of dietary fatty alcohols in Leach's storm petrel *Oceanodroma leucorhoa*. Journal of Experimental Zoology. 240(2):149-162.

Shading of *Euglena* growing on yield alcohol may have caused the accumulation of paramylon and lowered synthesis of amino acids and protein which are essential for the cell growth. The bleached mutant has been shown to adapt to myristyl alcohol medium after several transfers and an increase in $(NH_4)_{Soldiering4}$ concentration. The mutant may induce an ability to synthesize amino acids from myristyl alcohols by this adaptation.

Prahl, F. G., G. Eglinton, E. D. S. Corner, et al. 1985. Fecal lipids released by fish feeding on zooplankton. Journal of the Marine Biological Association of the United Kingdom. 65(2):547-560.

Fatty acid (and therefore fatty alcohol?) moieties of C18-C20 virtually eliminated in digestion; higher chain lengths were enriched in the feces.

The feces of wax-fed (hexadecyl oleate) birds contain fatty alcohol and fatty acid, the products of wax hydrolysis.

*Ristau, E. & F. Wagner. 1983. Formation of novel anionic trehalose tetraesters from Rhodococcus erythropolis under growth limiting conditions. Biotechnol. Lett 5:95-100.

Romankevich, Ye. A., M. G. Bystrova, I. A. Nemirovskaya, et al. 1982. Composition of lipids of benthic sediments. Viniti. No volume number given. Pages 100-107.

A study was made of the upper layer (0-5 cm) of benthic sediments from a river system shelf. The lipids in the organic matter of the sediments fluctuated from 1.5 to 10.7%, averaging 3.5%, with fatty alcohols being one of the 7 lipid components. This article is in Russian and has not been translated.

Richterich, K., P. Gode, W. Guhl. 1985. Ecological evaluation of a new non-ionic anti-foaming agent. Fette Seifen Anstrichmittel. 87(10) 421-424.

The product discussed is a mixture of C12/C18 fatty alcohol with 10 EO butyl ether. In Germany, specific tests are required for biodegradability ("BiAs" reduction). For this product, the BiAs reduction was between 93 and 98%; a better degree than the minimum regulatory requirement of 80%. Closed bottle tests and a simulation of sewer plant/riverine environments demonstrated rapid biodegradation (time values are not given in abstract. The article is in German and has not been translated.)

Sabastiani, A., Simonetti, A. D., Borgioli, A., et. al. 1971. Behavior of synthetic detergents in soil. III. Soft detergents, microorganisms and soil. Nuovi Ann Ig Microbiol. 22(4):229-242.

This article is in Italian, with no abstract. Lack of other information may require this to be ordered and translated.

Sargent, J. R., C. C. E. Hopkins, J. V. Seiring, et al. 1983. Partial characterization of organic material in surface sediments from Balsfjorden, Northern Norway, in relation to its origin and nutritional value for sediment ingesting animals. Marine Biology (Berlin). 76(1):87-94.

Basin surface sediments were characterized to assess the nature and origin of the organic material present and its potential nutritive value for sediment ingesting animals. Fatty alcohols accounted for 30% of the non-saponifiable lipids and phytol alcohols accounted for 40% of the fatty alcohols. Small amounts of very long-chain fatty alcohols characteristic of terrestrial plants were present, but long-chain monounsaturated fatty alcohols characteristic of marine zooplankton were essentially absent.

No fatty alcohols n-chain-lengths of less than 13 carbons were detected in this experiment. It is possible that the extraction process volatilized the n-fatty alcohols with lower chain lengths (the shortest chain alcohol detected had a melting point near the temperature used in the extraction process and lower chain length compounds would be expected to be more volatile than longer straight-chain alcohols). The percentages of n-fatty alcohols recovered are presented below:

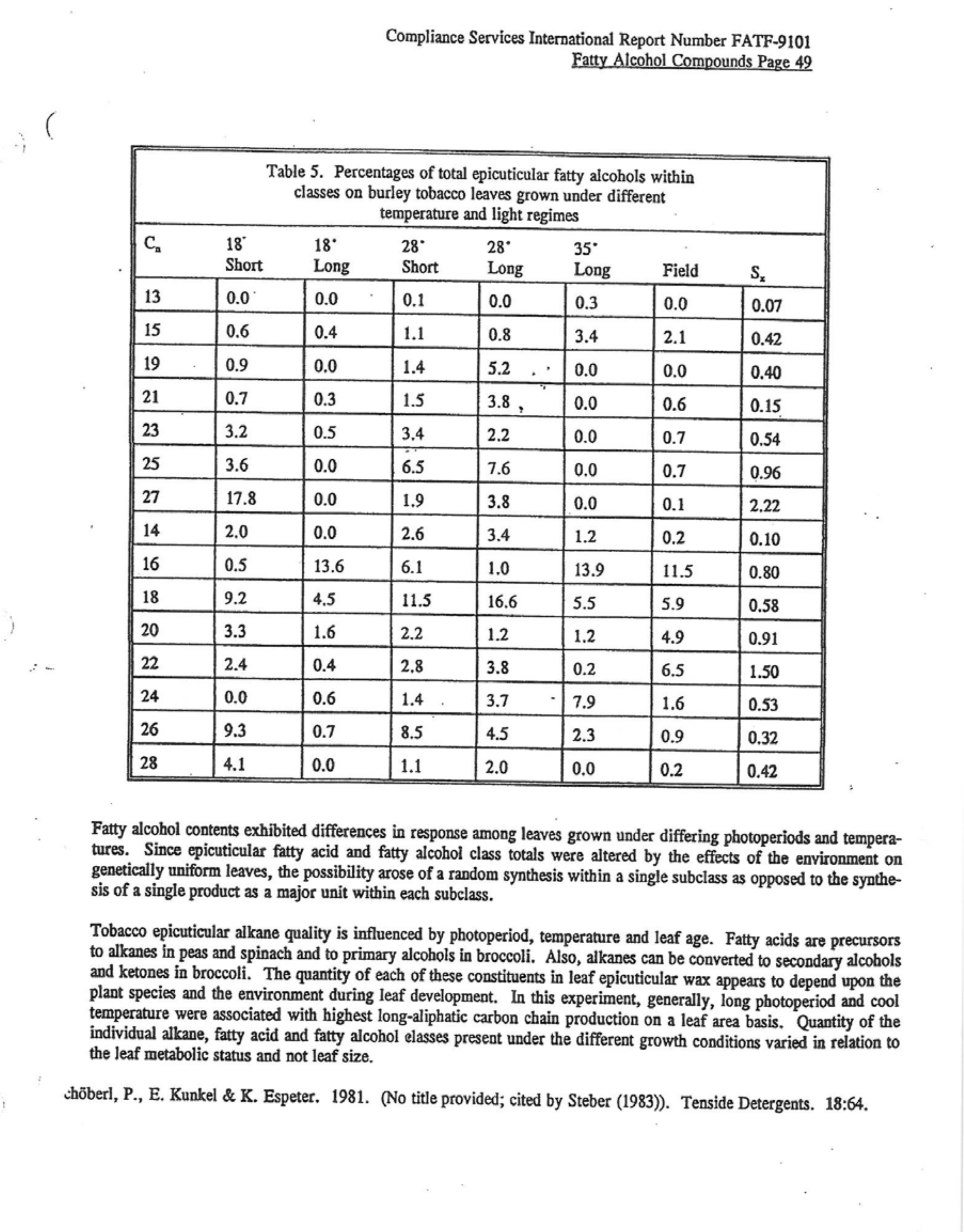


Table 5. Percentages of total epicuticular fatty alcohols within classes on burley tobacco leaves grown under different temperature and light regimes

C_n	18° Short	18° Long	28° Short	28° Long	35° Long	Field	S_x
13	0.0	0.0	0.1	0.0	0.3	0.0	0.07
15	0.6	0.4	1.1	0.8	3.4	2.1	0.42
19	0.9	0.0	1.4	5.2	0.0	0.0	0.40
21	0.7	0.3	1.5	3.8	0.0	0.6	0.15
23	3.2	0.5	3.4	2.2	0.0	0.7	0.54
25	3.6	0.0	6.5	7.6	0.0	0.7	0.96
27	17.8	0.0	1.9	3.8	0.0	0.1	2.22
14	2.0	0.0	2.6	3.4	1.2	0.2	0.10
16	0.5	13.6	6.1	1.0	13.9	11.5	0.80
18	9.2	4.5	11.5	16.6	5.5	5.9	0.58
20	3.3	1.6	2.2	1.2	1.2	4.9	0.91
22	2.4	0.4	2.8	3.8	0.2	6.5	1.50
24	0.0	0.6	1.4	3.7	7.9	1.6	0.53
26	9.3	0.7	8.5	4.5	2.3	0.9	0.32
28	4.1	0.0	1.1	2.0	0.0	0.2	0.42

Fatty alcohol contents exhibited differences in response among leaves grown under differing photoperiods and temperatures. Since epicuticular fatty acid and fatty alcohol class totals were altered by the effects of the environment on genetically uniform leaves, the possibility arose of a random synthesis within a single subclass as opposed to the synthesis of a single product as a major unit within each subclass.

Tobacco epicuticular alkane quality is influenced by photoperiod, temperature and leaf age. Fatty acids are precursors to alkanes in peas and spinach and to primary alcohols in broccoli. Also, alkanes can be converted to secondary alcohols and ketones in broccoli. The quantity of each of these constituents in leaf epicuticular wax appears to depend upon the plant species and the environment during leaf development. In this experiment, generally, long photoperiod and cool temperature were associated with highest long-aliphatic carbon chain production on a leaf area basis. Quantity of the individual alkane, fatty acid and fatty alcohol classes present under the different growth conditions varied in relation to the leaf metabolic status and not leaf size.

chöberl, P., E. Kunkel & K. Espeter. 1981. (No title provided; cited by Steber (1983)). Tenside Detergents. 18:64.

*Schöberl, P. 1982. Mikrobieller Abbau eines Kokosfettalkohol-ethoxylates durch *Acinetobacter lwoffi*, Stamm ML. Tenside Detergents 19:329-3339.

*Schnitzer, M., C.A. Hindle, M. Meglic. 1986. Supercritical gas extraction of alkanes and alkanoic acids from soils and humic materials. Soil Science Soc. Am. J50:913-919.

✓*Sever, J., P. L. Parker. 1969. Fatty alcohols normal and isoprenoid in sediments. Science (Washington). 164(388-3):1052-1054.

> Normal long-chain fatty alcohols were identified in marine sediments and evaluated as indicators of sediment age. Both normal and isoprenoid alcohols were found in recent and ancient sediments. Sediments from three different recent and three different ancient sediments were analyzed by gas chromatography. Ancient sediments were: Miocene age, from an outcrop in the Philippine Islands; Eocene, from Green River (Colorado) Shale; and Upper Cretaceous, from an outcrop near Austin, Texas. Recent sediments were: Baffin Bay, a hypersaline arm of Laguna Madre off Corpus Christi, Texas; Gulf of Mexico, off Port Aransas, Texas; and San Nicholas Basin, off the coast of Southern California.
>
> Recent sediments, even where terrestrial run-off is minimal, contain normal saturated alcohols with 12 to 26 carbons. Alcohols with both even and odd numbers of carbon atoms were present. In addition, normal, monomethyl and isoprenoid long-chain hydrocarbons, alcohols and fatty acids were present. The amounts of alcohols found in recent sediments were from one order of magnitude less to the same order of magnitude as the concentrations of fatty acids.

SEVER TABLE: Concentration
(Parts of alcohol per million parts of dry sediment)
of the Normal Alcohols in Sediments

ALCOHOL	BAFFIN BAY	GULF OF MEXICO	SAN NICHOLAS BASIN	MIOCENE AGE	EOCENE AGE	UPPER CRETACEOUS
n-dodecanol	1.00	-	-	-	-	-
n-tetradecanol	1.40	0.36	3.00	1.75	3.20	1.30
n-hexadecanol	0.99	1.08	2.20	0.14	0.50	1.10

> Analytical confirmation was conducted to assure that the extraction procedure did not create any artifacts. Fatty alcohols in sediments probably have their origin in the marine life of the areas studied. Baffin Bay, where C_{12} alcohol was detected, normally receives very little fresh water and is often twice as saline as normal sea water. Such restricted run-off would probably not transport enough terrestrial organic matter to account for the uniform concentrations of alcohols observed in the Bay sediments. The author did not speculate as to which marine organisms were involved in the formation of organic compounds studied here, although he

proposed that bacteria may be involved. Isoprenoid alcohols which were detected suggested that these products were side chains of chlorophyll and possibly were partially decayed deposits of plant material.

*Shadiakhy, A., H. Stage. 1981. Influence of double bonds and branchings on vapor pressure as well as the volatility relations of fatty acids, fatty acid esters, fatty alcohol mixtures or mixtures of the corresponding carbohydrates. Fette Seifen Anstrichmittel. 83(11):431.

This article is in German and is apparently presented only as a meeting abstract. There are no references. It may be interesting to pursue if no other information on volatility is discovered.

✓*Singer, M. E. V., W. R. Finnerty. 1990. Physiology of biosurfactant synthesis by *Rhodococcus* species H13-A. Canadian Journal of Microbiology. 36(11):741-745.

The commercial production of biosurfactants from microbial activity is of interest. Biosurfactants are surface-active agents produced by bacteria, yeasts, and fungi and include such products as fatty acids, glycerides, phospholipids, lipopeptides and antibiotics. Biosurfactants produced by microorganisms are generally considered to represent a mechanism for the solubilization or emulsification of water-insoluble substrates to facilitate transport by the cells.

This investigation describes the identification of a biosurfactant-producing bacterium and the general physiology of biosurfactant synthesis in *Rhodococcus* species H13-A. *Rhodococcus* species H13-A was isolated from soil after several passages on hexadecane enrichment medium. Extracellular glycolipid synthesis by *Rhodococcus* species H13-A occurred following growth on decane through octadecane as sole sources of carbon and energy. The highest levels of glycolipid results from growth on dodecane, tridecane and tetradecane. No evidence was obtained of cell lysis. The synthesis and release of glycolipid into the growth medium are linked to nitrogen limitation.

Other studies were referenced which have investigated this process in other organisms. Other surface-active glycolipids are synthesized by actinomycetes during growth on alkanes, including trehalose mycolates by *Arthrobacter paraffineus*.

✓*Sinniah, B. 1983. Insecticidal effect of aliphatic alcohols against aquatic stages of *Aedes* mosquitoes. Transactions of the Royal Society of Tropical Medicine and Hygiene. 77(1):35-38.

Long chain fatty alcohols (C_{12}-C_{20}) can be applied to water so that a monomolecular layer is formed on the surface. Earlier research showed that a surface layer of lauryl alcohol (C_{12} alcohol) kills all larval stages of *Culex quinquefasciatus*. The aim of the current study was to investigate the effectiveness of some aliphatic alcohols as insecticides against the aquatic stages of *Aedes aegypti* (L.) and *Aedes scutellaris* (Walker).

The article also presents some information on the properties of the compounds investigated. Compounds of interest and their properties given are listed below:

ALCOHOLS TESTED AGAINST THE AQUATIC STAGES OF MOSQUITOS					
ALCOHOL	NO. OF CARBONS	PHYSICAL CHARACTERISTICS	SOLUBILITY IN WATER	MODECULAR WEIGHT	MELTING POINT
1-decanol	C10	Liquid	Insoluble	158.3	-26.6°C
1-decanol	C10	Liquid	Insoluble	172.3	15.2°C
1-dodecanol	C12	Liquid	Insoluble	186.3	23.0°C
1-tetradecanol	C14	Solid Wax	Insoluble	214.3	39.0°C
1-hexadecanol	C16	Solid Wax	Insoluble	242.2	49.0°C

The alcohols tested ranged from chain lengths of C_2-C_{18}, but there were no straight chain alcohols tested below the chain length of decanol. Compounds were tested at concentrations equivalent to 1, 2, 4, 8, 10, 20, 40, 80, 100 and 200 liters/hectare, at test temperatures of 25 to 27 degrees C. Larvae, pupae and eggs were tested. Results are shown below:

24-hour LD_{50} and LD_{90} (%) for various alcohols tested against eggs, first, third and fourth instar larvae and pupae of *Ae. aegypti* and *Ae. scutellaris*

Alcohol Tested	Egg or Larval state	Lethal dose in litres/hectare			
		Ae. aegypti		*Ae. scutellaris*	
		LD^{50}	LD^{90}	LD^{50}	LD^{90}
1-decanol	Egg	3	5	3	5
	L1	3	5	3	4
	L3-L4	3	6	3	6
	pupae	2	3	2	3
1-undecanol	Egg	4	6	4	6
	L1	3	5	3	5
	L3-L4	4	6	3	6
	pupae	4	5	4	5
1-dodecanol	Egg	4	7	4	7
	L1	4	6	4	6
	L3-L4	4	7	4	7
	pupae	3	6	4	6
1-tetradecanol	Egg	20	4	21	42
	L1	285	312	280	315
	L3-L4	285	352	309	335
	pupae	59	86	62	92
1-hexadecanol	Egg	37	54	40	59
	L1	312	396	296	385
	L3-L4	356	436	321	409
	pupae	86	132	91	140

In control trials, the solvent (hexane) showed no harmful effect on the larvae. Trials with more than 10% mortality in the control were not used in the determination of an LC_{50}. This author reports work by Miller and Maddock (1970) which tested a number of alcohols and found only one that was effective (cinnamyl alcohol). Most of the alcohols tested were of lower carbon chain length, and they tend to evaporate before they have a chance to cause damage to the tissues of mosquitoes. Very long chains were ineffective except at very high dosages. In separate studies also reported here, Lorenzen and Meinke (1968) found that larvae fed 1-hexadecanol did not die. It was speculated that mortality was induced by the breakdown of cuticular lipids. thus as with most oils, the surface-active properties may be responsible for the ovicidal activities of these compounds.

Simoneit, B.R.T. 1977. Organic matter in eolian dusts over the Atlantic Ocean. **Mar. Chem.** 5:443-464.

Simoneit, B. R. 1989. Organic matter of the troposphere V: Application of molecular marker analysis to biogenic emissions into the troposphere for source reconciliations. Journal of Atmospheric Chemistry. 8(3):251.

Aerosols from rural and remote areas in the Western US, South America, Nigeria, and Australia were analyzed for "atmospheric detritus" content. All samples contained predominantly plant waxes. The loadings of hydrocarbons included fatty alcohols at 10 to 1650 ng/m^3. Higher molecular weight lipids contributed a major portion of the organic carbon in samples from remote and rural areas. They are therefore important indicators for regional biogenic sources in the global cycling of organic carbon.

✓*Simoneit, B.R.T. 1979. Biogenic lipids in eolian particulates collected over the ocean. In **Proceedings: Carbonaceous Particles In the Atmosphere.** (Ed. by T. Novakov), pp. 233-244. NSF-LBL

*Simoneit, B. R. T., M. A. Mazurek. 1982. Organic matter of the troposphere. II. Natural Background of biogenic lipid matter in aerosols over the rural western United States. Atmos. Environ. (England). 16(9):2-139-2159.

This research concluded that higher plant waxes were the predominant matural components in the lipid fractions ($>C_{15}$) of aerosols sampled over rural and oceanic regions. These compounds are important components in the global recycling of organic carbon. Volatile natural organic compounds have been identified and quantified in rural, oceanic and urban aerosols.

This study of aerosols from the Western United States was initiated for the threefold purpose of: (1) comparison of the area extremes; (2) characterization of the solvent soluble fractions; and (3) evaluation of relative organic aerosol contributions from natural biogenic emissions and anthropogenic sources. Aerosol samples were acquired from the rural and urban sites by filtration of the ambient air using a standard high volume air sampler fitted with a quartz fiber filter. Representative samples of vegetation were taken in various areas to provide a composite for *in situ* wax analysis. Analysis was by gas chromatography and GC/MS.

The concentration range for the total lipids (hydrocarbons, fatty acids, fatty alcohols, trace amounts of ketones, etc) was discovered to be from 90 to 3600 ng m^{-3} with the fatty alcohols and other polar lipids at a concentration of 200 to 2000 ng m^{-3}. The yield of lipid material for these samples represented up to 10% of the total organic carbon. The total fatty alcohol composition was indicative of derivation from vascular plant waxes, especially forest and grassland types of plants. The saw-toothed distribution of the chain lengths (odd > even) compared directly with the n-alkane distributions in specific plant communities. The total fatty alcohol fractions included chain lengths of C_{10} to C_{33}, with the middle of this range predominating.

In this particular investigation, the C_1 to C_{20} homologs were largely lost due to evaporation (according to their boiling points) in the environment and/or in the experimental procedure, or were separated by distillation in the refining process. Absolute concentrations of the homologs $< C_{20}$ in these aerosol samples are not accurate, but qualitative comparisons can be made.

From the information above, the authors have concluded that the concentration of shorter chain fatty alcohols is equal to or greater than the concentration of fatty alcohols which are $> C_{20}$. Typical distribution of fatty alcohols which were quantifiable are shown below, and include data on chain lengths of 10 to 35 carbons.

The author speculates that the homologs $< C_{20}$ may be derived from microbial sources since they are not prevalent in fresh vascular plant waxes. The predominant alcohols in all samples were normal fatty alcohols with minor amounts of secondary alcohols and varying amounts of phytosterols. The dominance of C_{26} and C_{28} chain lengths in the aerosol samples compares in general with the distributions for grass wax. These data indicate that fatty alcohols from plant waxes preserve their characteristic fingerprint in aerosols and are a major fraction of the lipid material.

Procedural blanks were analyzed to assess the accuracy of the extraction and analytical procedures. Some contaminants were discovered and included minor amounts of n-fatty acids and residual phthalate esters, but no fatty alcohols.

✓*Solberg, Y. 1989. A literature review of the lipid constituents of higher fungi. New investigations of *Agaricales* species. International Journal of Mycology and Lichenology. 4(1/2):137-154.

The chemical contents of several higher fungi were studied. Extraction and concentration lead to isolation of fractions containing aliphatic and aromatic hydrocarbons, fatty alcohols and fatty acids. Fatty acids (and fatty alcohols?) were predominantly of C_{16} to C_{18} chain length. The details of findings by species tested are provided, with the discussion centering on fatty acids.

✓*Speel, H. C. 1963. Foam, pollution and biodegradability. Journal of the American Oil Chemist's Society. 40(7):4,12,13,15.

This article presents general information but no original research. The biodegradability of detergents is the topic matter, but their origin (alkyl benzene sulfonates vs. alkyl sulfates) determines their behavior. The straight chain fatty alcohol sulfates, whether derived from natural alcohols, natural fats or oils, or from ethylene by Ziegler-type processes, are generally considered to be completely biodegradable. Sodium lauryl sulfate (C_{12}), for example, disappears in less than 3 days (in water). The overall process was oxidative. In general, the lower molecular weight species of each detergent type produces more foam on agitation, but degrades more rapidly than the higher molecular weight species.

✓*Steber, J., P. Wierich. 1983. The environmental fate of detergent range fatty alcohol ethoxylates. Biodegradation studies with a 14C labelled model surfactant. Tenside Detergents. 20(4):183-187.

In order to solve several outstanding problems in the biodegradation of a model fatty alcohol ethoxylate (labelled separately in the alkyl as well as the EO chain) was elucidated in a continuous activated sludge system using simulation tests and die-away tests. Because the alkyl chain was labeled, some conclusions can be drawn about the fate of the stearyl alcohol side chain. The [1-^{14}C] stearyl alcohol = 7 EO had a specific activity of 19.2 mCi/g; the radiochemical purity was 98%. Only the results of the experimentation conducted on the labeled alkyl compound is discussed here.

The simulation tests used a model plant which was a miniature continuous flow activated sludge unit constructed according to Swisher. The die-away tests were discontinuous tests analogous to the OECD Screening Test and were performed in shake flasks modified to a closed system. In the simulated plant study, after a working-in period of approximately two weeks the plant was fed for about one week with synthetic sewage containing one of the radiolabeled surfactants. As expected, the carbon in the 1-position of the alkyl-labeled compound was mineralized to $^{14}CO_2$ to a greater extent than the EO-moiety of the analogous ^{14}C-EO surfactant. Mineralization rates were 50 to 60% after 2 to 3 days of ^{14}C-feeding, with a slightly increasing tendency. The radioactivity of the effluent from the alkyl-labeled surfactant only amounted to about 6% (undegraded). When results were adjusted for recovery (93.8%), it was reported that 99% of the fatty alcohol ehtoxylates present in the influent incurred microbial attack within 3 hours' retention time in the model plant.

Degradation of the [1-^{14}C] stearyl alcohol ethoxylate led to predominantly (90%) acidic metabolites. This fraction of degradation products was mainly composed of carboxylated polyethylene glycols. The neutral metabolites as well as the acidic biodegradation intermediates were reported as highly biodegradable. 25-30% of the sludge radioactivity accounted for undegraded residual surfactants. The main portion of sludge radioactivity (70%) corresponded to about 27% of the initial radioactivity and consisted of bacterial biomass. The lipid fraction of the sludge from the [1-^{14}C] alkyl ethoxylate experiment had a considerably higher radioactivity than sludge from the ring labeled experiment. This was explained as a consequence of microbial degradation of the alkyl-chain via β-oxidation according to general biochemical pathways, resulting in the production of acetyl units, which represent the elementary precursors for fatty acid biosynthesis.

The relatively high surfactant content in the sludge may result from the comparatively low water solubility of stearyl alcohol + 7 EO. Additionally, the hydrophilic EO-chain of alcohol ethoxylates exhibits a slower biodegradation rate than the hydrophobic part of the surfactant molecule. The faster biodegradation of the alkyl chain is clearly shown by the fact that the intermediates of the [1-^{14}C] stearyl alcohol ethoxylate biodegradation found in the effluent consisted largely of higher EO-numbered acidic polyethylene glycols which obviously must contain a small ^{14}C labeled moiety. In addition, it is evident that these polyethylene glycol carboxylates can only arise if degradation of the alkyl chain starts at the terminal methyl group. This is in accordance with conclusions drawn by other authors.

The alkyl chain of the fatty alcohol ethoxylate exhibited an ultimate biodegradation of about 75%. The actual extent of degradation may exceed this value for two reasons: (1) the steady state mineralization rate was higher than the balanced value of total $^{14}CO_2$-evolution and (2) an undervaluation results from the ^{14}C-labeling position in connection with the degradation mechanism. The biodegradation begins at the terminal methyl of the alkyl chain, so that in this case, the alkyl carbon in position 1 represents the last carbon being transformed.

From these studies it was concluded that the biodegradation of stearyl alcohol + 7 EO formed no recalcitrant metabolites and would be expected to completely biodegrade under primary sewage treatment, as well as by self-purification processes in surface waters.

Steber, J., P. Gode, W. Guhl. 1988. Fatty alcohol sulfates: the ecological evaluation of a group of important detergent surfactants. Fett Wissenschaft Technologie. 90(1):32-38.

> This group of alcohol detergents showed a very rapid and complete biodegradation with respect to primary breakdown and ultimate degradability (mineralization and assimilation). This was true under both aerobic and anaerobic conditions. The similarity of these processes to those for straight-chain fatty alcohol is not explained in the abstract for the article (the article is in German and has not been translated).

✓*Steber, J., P. Wierich. 1985. Metabolites and biodegradation pathways of fatty alcohol ethoxylates in microbial biocenoses of sewage plants. Applied and Environmental Microbiology. 49(3):530-537.

The results of Steber (1983) and subsequent experimentation are discussed and indicate that there is a faster degradation of the alkyl than the polyethylene glycol moiety and that there are two distinct primary degradation mechanisms acting simultaneously in the microbial biocenoses: intramolecular scission of the surfactant as well as ω- and β-oxidation of the alkyl chain. In this report, a picture of the microbial pathways that bring about ultimate biodegradation of fatty alcohol ethoxylates in the environment were made. Studies were conducted in a model continuous flow activated sludge plant similar to that described by the OECD Confirmatory Test.

Stearyl alcohol ethoxylate was labeled on the alcohol or EO portion of the molecule. The information presented here concentrates on the results obtained with the stearly-labeled compound. [1-^{14}C] stearyl alcohol-7 EO of 19.2 mCi/g specific activity and radiochemical purity of 98% was used. The OECD model sewage treatment plant had a 3 hour mean retention time. Radioactivity of the effluent from the alkyl-labeled model surfactant amounted to 9% of the initial activity. Only small amounts (1% of the initial level) of each compound could be attributed to intact parent surfactants. After degradation of the chain-labeled compound, largely acidic compounds were abstained.

A fast degradation of the fatty alcohol moiety of the surfactant, beginning with terminal methyl group and slowing down before the radiolabeled C-1 is reached. The terminal oxidation of the alkyl chain (ω-oxidation) and subsequent stepwise removal of C_2 units at a time by β-oxidation is presented as the fatty alcohol chain metabolic process. The resulting products represent the elementary precursors of fatty acid biosynthesis.

*Steffens, G. L., T.C. Tso & D.W. Spaulding. 1967. Fatty alcohol inhibition of tobacco axillary & terminal bud growth. J. Agr. Food Chem. 15:972-975.

*Stephens, U. 1958. Research and Experiments in Evaporation Reduction. Journal of American Water Works Association. 50:846-854.

*Stevenson, F.J. 1982. Humus Chemistry, Genesis, Composition Reactions. Wiley, New York.

*Still, G. G., D. G. Davis & G. L. Zander. 1970. Plant epicuticular lipids: alternation by herbicidal carbamates. Plant Physiol. 46:307-314.

*Suzuki, T., K. Tanaka, I. Matsuhara et al. 1969. Trehalose lipid and α-branched hydroxy fatty acid formed by bacteria grown on n-alkanes. Agric. Biol. Chem. 33:1619-1627.

Scharer, D.H., L. Kravetz & J.B. Carr. 1979. Biodegradation of non-ionic surfactants, p. 61-66. Proc. of the TAPPI Env. Conf. TAPPI, Atlanta.

Simoneit, B.R.T. 1978. The organic chemistry of Marine Sediments. In Chemical Oceanography, 2nd ed. (edited by J. P. Riley & R. Chester) Vol 7:233-311. Academic Press, New York.

*Tobin, R.S., F.I. Onuska, B.G. Brownlee et al. 1976. The application of an ether cleavage technique to a study of the biodegradation of a linear alcohol ethoxylate noniomic surfactant. Water Res. 10:529-535.

*Vashon, R.D. & B.S. Schwab. 1982. Mineralization of linear alcohol ethoxylates & linear ethoxy sulfates at trace concentrations in estuarine water. Environ. Sci. Technol. 16:433-436.

Venkatesan, M. I., I. R. Kaplan. The lipid geochemistry of Antartic marine sediments: Bransfield Straight. Marine Chemistry. 21(4):347-376.

> In sections of sediment cores from the area titled, the resolvable lipid compound classes generally occur in the following order of abundance: n-fatty acids > n-alkanes > n-alcohols > sterols > PAH. The distribution of various lipid components indicate that they are principally from marine autochthonous sources, largely from diatoms and bacteria and to a lesser extent from dinoflagellates.

*Wilkinson, R.E. & M.J. Kasperbauer. 1972. (No title provided; cited by Wilkinson & Kasperbauer(1980)). Phytochemistry. 11:2439.

✓*Wilkinson, R.E. & W.S. Hardcastle. 1970. EPTC effects on total leaflet fatty acids and hydrocarbons. Weed Sci. 18:125-128.

*Wilkinson, R.E. 1970. Sicklepod fatty acid response to photo period. Plant Physiol. 46:463-465.

*Wang, T.S.C. 1969. Soil organic matter as cause of increased soil productivity or otherwise phytotoxicity. Int. Rice Com. Newsletter 18(2):23-26.

Wilkinson, R. E., M. J. Kasperbauer. 1980. Effect of light and temperature on epicuticular fatty acid and fatty alcohol of tobacco *Nicotiana tabacum Cultivar Burley-21*. Phytochemistry (Oxford). 19(7):1379-1383.

✓*Wilkinson, R. E. 1974. Sicklepod surface wax response to photoperiod and S-(2,3-dichloroallyl)diisopropylthiocarbamate (diallate). Plant Physiology. 53(2): 269-275.

The influence of herbicides on the deposition of epicuticular waxes and the components of such waxes has been studied in several species. In a study on peas, diallate was found to inhibit wax synthesis quantitatively but did not qualitatively influence lipids except for the primary alcohols. The current investigation evaluates the wax deposition and its components in sicklepod leaf tissue in order to determine the influence of photoperiod and various diallate concentrations on epicuticular wax formation and content.

Total fatty alcohol content of sicklepod leaflet epicuticular waxes was significantly increased over the untreated control by 0.28 kg/ha diallate and significantly decreased by 1.12 kg/ha diallate. Between these two extremes, the intermediate application rates of diallate were not significantly different from the untreated control. This general pattern was repeated in all structural classes of fatty alcohols present in the epiculticular waxes of sicklepod leaflets with the exception of the antesio-fatty alcohols which were significantly decreased by all application rates of diallate.

Synthesis of fatty acids was shown to be greatly inhibited by diallate with the exception of four constituents ($C_{14:1}$, $C_{16:1}$, $C_{20:1}$ and C_{122}). Conversely, the synthesis of all fatty alcohols was stimulated by 0.14 and 0.28 kg/ha diallate with the exception of C_{A17} and C_{122}. These results suggest that the biochemical relationships between the various lipid classes is not completely elucidated. In addition, epicuticular fatty alcohol content was responsive to photoperiod in a different pattern from that of the fatty acids. The two patterns were not reciprocal. The influence of diallate on individual n-fatty alcohols which are in our range of interest is shown below.

Each value is the average of 20 determinations; five from each of 10-, 12-, 14-, 16-hr photoperiods.

Table IV. Influence of Diallate on the Individual Epicuticular Fatty Alcohol Constituents

	Diallate (kg/ha)				
	0	0.14	0.28	0.56	1.12
10	100	725	1071	207	
11	100	312	343	152	2
12	100	260	232	189	
13	100	683	238	190	1
14	100	270	215	59	
15	100	230	400	8	
16	100	113	275	46	10
18	100	167	230	64	16

Fatty alcohol content of the external wax of sickelpod leaflets demonstrated a different photoperiod response from that of the fatty acids. The total surface fatty alcohol content was minimal under 12-hour photoperiods and maximal under 16 hour photoperiods. Earlier experiments with thiocarbamate herbicides noted a reduction of cuticular waxes upon herbicide exposure. Sublethal application rates of EPTC were reported to stimulate total fatty acid synthesis and reduce alkane synthesis in the sicklepod. Fatty acids were converted to alkanes in pea or spinach and to alcohols in broccoli. The presumption that fatty acyl moieties produced by fatty acid synthetase serve as general intermediates to the various lipid classes found in plant cuticular waxes has gained credence. Plant cuticular waxes have been proposed as the end product of metabolism in the epidermis.

Wilkinson, R. E. 1973. Diallate and photoperiod influence on epicuticular fatty acid and fatty alcohol content. *Abstracts*, 1973 Meeting of the Weed Science Society of America (unnumbered).

In experiments with sicklepod, a common weed species, it was found that herbicide application and varying photoperiods could result in variations in plant fatty alcohol content. Fatty alcohol contents were highest under 10 hour photoperiods. Previous experiments showed that age and temperature could also induce variations.

✓*Wheeler, J. J., H. Seltman, A. G. Motten. 1991. The mode of action of fatty alcohols on leaf tissue. Journal of Plant Growth Regulation. **10**(3):129-137.

Mixtures of C_8 and C_{10} fatty alcohols, which usually include small amounts of the C_6 and C_{12} alcohols, formulated with polyoxyethylene (20) sorbitan mono-oleate (SMO), are among the agents used in the control of axillary buds ("suckers") in the culture of tobacco. Fatty alcohols as emulsions are contact herbicides; they are not translocated, but instead destroy tissue at the point of contact. In these studies, the fatty alcohol emulsion was applied at label rates and it was found to pass through the cuticle without disrupting it. The plasma membranes of subtending cells were altered so that, in time, bud tissues were desiccated and growth of the sucker was controlled. Eight plant species/varieties were used in this investigation: *Nicotiana tabacum* L. and *Nicotiana tabacum* L. cv Xanthi (tobacco); *Nicotiana glauca* L.; *Ficus elastica* Roxb. ex Hornam.; *Taraxacum officinale* L.; *Lamium amplexicaule* L.; *Rosa sp.*; and *Elodea sp.*. The mode of action in each plant type was identical; the induction of desiccation apparently was dependent upon the time it took fatty alcohol to cross the leaf cuticle (thus the selective desiccation of axillary buds with incompletely developed cuticular surfaces).

Wertz, P. W., D. T. Downing. 1989. Integral lipids of human hair. Comparative Biochemistry and Physiology B: Comparative Biochemistry. 92(4):759-762.

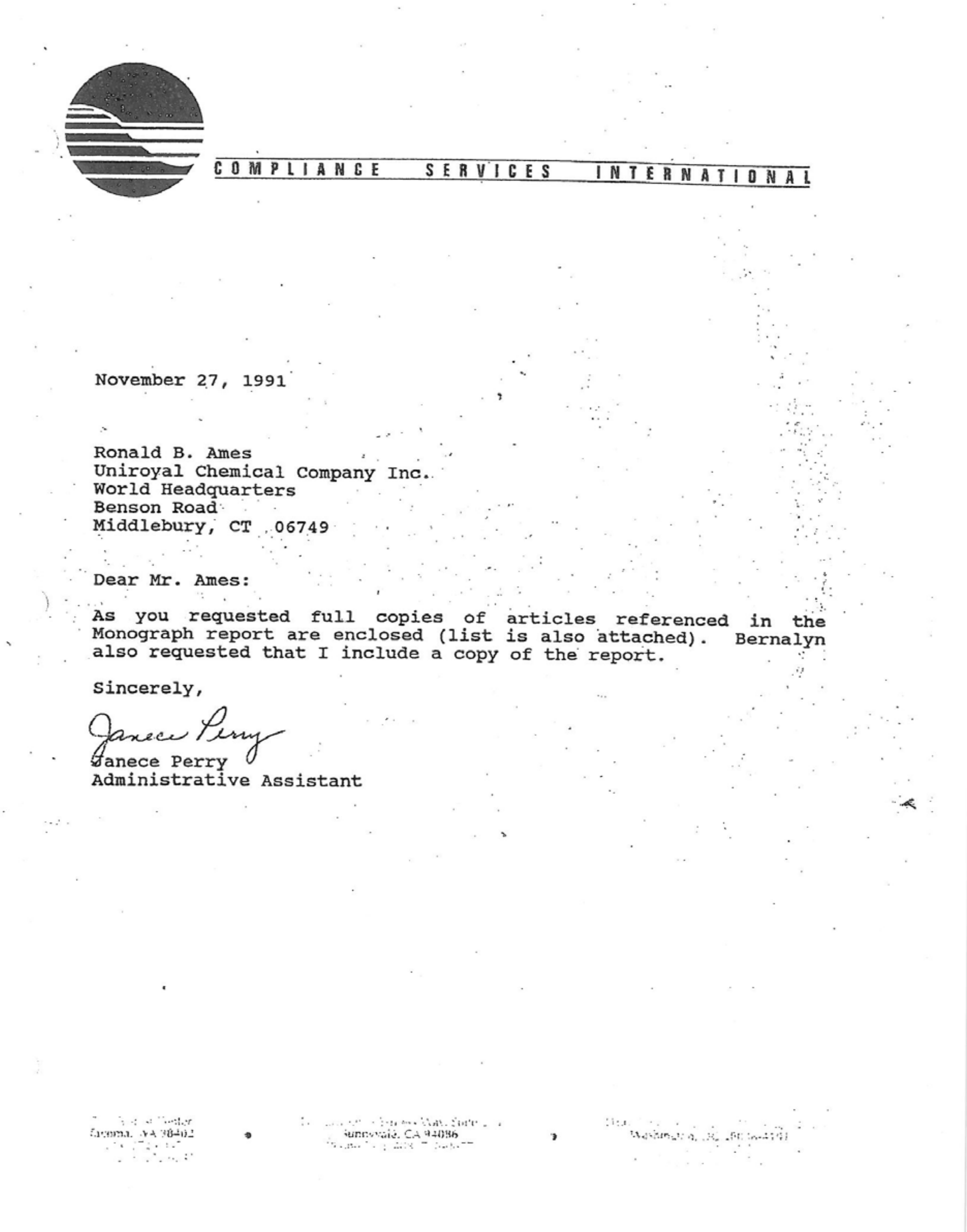
A series of quaternary ammonium compounds that are esters of betaine and fatty alcohols with hydrocarbon chain lengths of 10 to 18 carbon atoms were tested with respect to antimicrobial activities and rates of hydrolysis. The hydrolysis products were normal human metabolites.
It has been demonstrated that hair contains lipids . . . including fatty alcohols at levels of trace to 0.2 mg/g.

The reason for variance in growth rates from one compound to another was not clear. The alcohols with chain lengths of 5 to 11 carbons inhibited photoautotrophic growth completely, and killed the cells. Other varieties of *Euglena gracilis* have been reported to grow on these middle carbon-chain-length alcohols.

There was a relationship between growth and the intracellular content of paramylon, the reserve polysaccharide of *Euglena*. In the presence of myristyl alcohol, when cells were shaded growth stopped, but alcohol was still assimilated and paramylon was increased in concentration to up to twice that of control light cells.

The mechanism of photoassimilation of C_{14}-alcohol (myristyl alcohol) was strictly light dependent; however, DCMU, an inhibitor of photosynthetic electron transfer, did not inhibit growth completely. With the bleached mutant *Euglena*, a long lag-phase extending more than 10 days occurred before growth started under illumination, and the final cell yield was about half that observed with wild-type cells. Growth on myristyl alcohol was almost saturated at light intensities of 600-1000 lx in comparison to autotrophic growth which increased with light intensities to at least 2000 lx.

Biosynthetic hypotheses suggest that short chain fatty-acid synthesis occurs with elongation of the aliphatic chain to long-carbon chains. Unsaturate, even-carbon numbered saturates, odd-carbon numbered saturates, and branched chain aliphatic units are derived from deaminated valine and isoleucine. Then, fatty acids are converted to alcohols and alkanes. Thus, the total variability of epicuticular wax quality and quantity reflects the activity of the individual enzymatic processes as they are affected by each environmental condition. These processes include but are not limited to: aliphatic carbon chain synthesis, desaturation, reduction and other modification, amino acid metabolism, and the multiplicity of factors influencing leaf growth.



COMPLIANCE SERVICES INTERNATIONAL

November 27, 1991

Ronald B. Ames
Uniroyal Chemical Company Inc.
World Headquarters
Benson Road
Middlebury, CT 06749

Dear Mr. Ames:

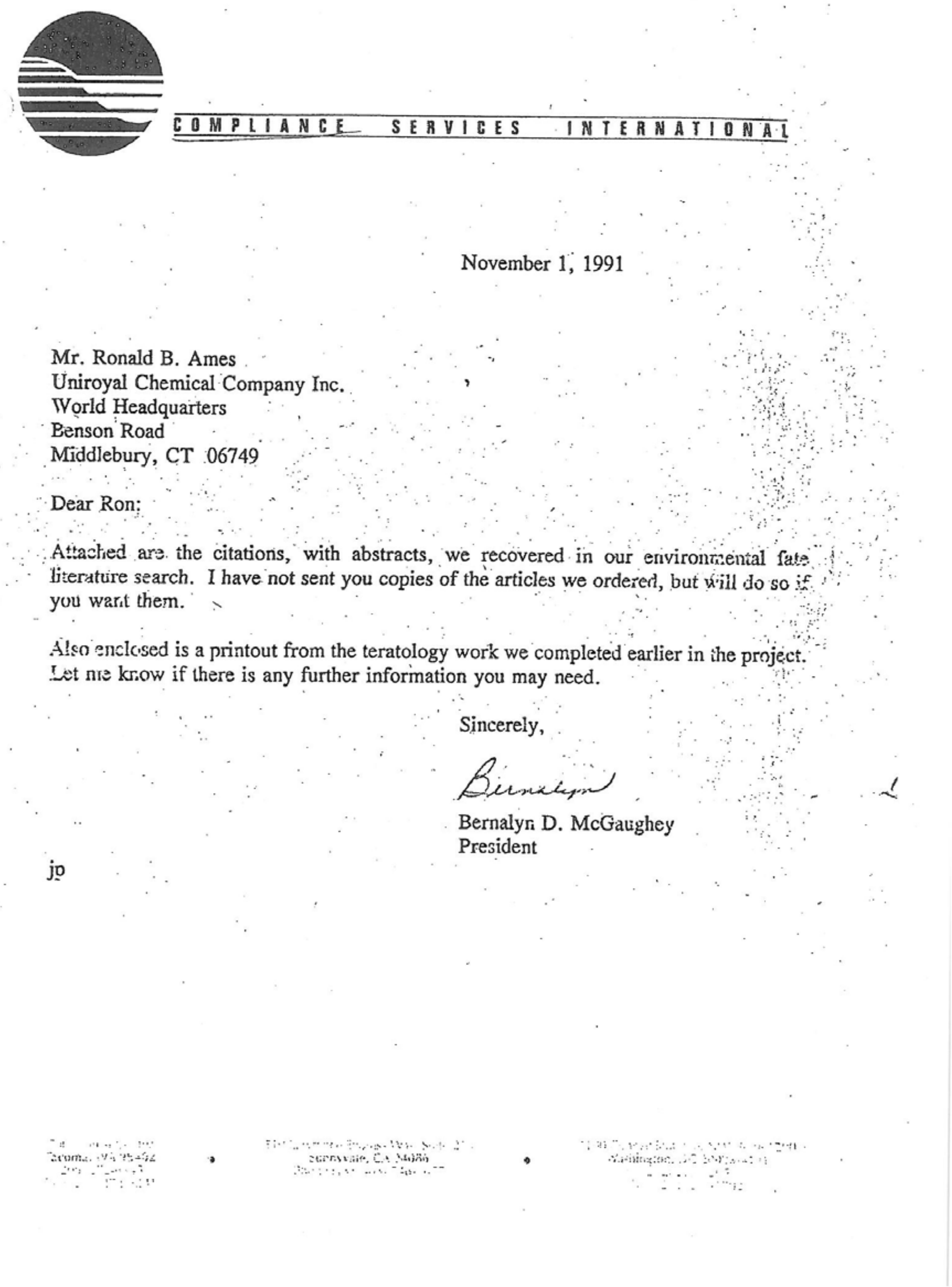
As you requested full copies of articles referenced in the Monograph report are enclosed (list is also attached). Bernalyn also requested that I include a copy of the report.

Sincerely,

Janece Perry

Janece Perry
Administrative Assistant

Tacoma, WA 98402 • Sunnyvale, CA 94086 • Washington, DC



COMPLIANCE SERVICES INTERNATIONAL

November 1, 1991

Mr. Ronald B. Ames
Uniroyal Chemical Company Inc.
World Headquarters
Benson Road
Middlebury, CT 06749

Dear Ron:

Attached are the citations, with abstracts, we recovered in our environmental fate literature search. I have not sent you copies of the articles we ordered, but will do so if you want them.

Also enclosed is a printout from the teratology work we completed earlier in the project. Let me know if there is any further information you may need.

Sincerely,

Bernalyn

Bernalyn D. McGaughey
President

jp

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Reregistration Eligibility Decision for Aliphatic Alcohols

March 2007

United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508P)

EPA 738-R-07-004

EPA Reregistration Eligibility Decision for Aliphatic Alcohols

Reregistration Eligibility Decision (RED) for Aliphatic Alcohols
List D
Case No. 4004

Approved by: ______________________
Date: ______________________
Debra Edwards, PhD., Director
Special Review and Reregistration Division

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Glossary of Terms and Abbreviations

ai	Active Ingredient
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
DCI	Data Call-In
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
GENEEC	Tier I Surface Water Computer Model (Estimated Aquatic Environmental Concentrations)
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
N/A	Not Applicable
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs ppb Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts per Million
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RQ	Risk Quotient
TGAI	Technical Grade Active Ingredient
UV	Ultraviolet
WPS	Worker Protection Standard

ALIPHATIC ALCOHOLS TEAM
Office of Pesticide Programs:

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Ecological Fate and Effects Risk Assessment
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Biological and Economics Analysis Assessment
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Risk Management
Kevin Costello
Tom Moriarty
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Abstract

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for the Aliphatic Alcohols case 4004 and is issuing its risk management decision. Currently, case 4004 consists of four active ingredients. Three of these active ingredients, 1-octanol, 1-decanol and a mixture of aliphatic alcohols described as “fatty alcohols,” are used as plant growth regulators on tobacco. The fourth, 1-dodecanol (also known as lauryl alcohol), is registered as a Lepidopteran pheromone/sex attractant in pear and apple orchards.

A tolerance reassessment was performed in 2002 for the use of 1-dodecanol as a pheromone. In that assessment of potential human exposure and dietary risk, the Agency concluded, “the tolerance exemption for Lepidopteran pheromones has been reassessed and is in compliance with the FQPA .” Neither a handler nor post-application (reentry) occupational assessment has been conducted for any uses of aliphatic alcohols of case 4004, because no dermal, oral, or inhalation endpoints of toxicological concern have been identified.

The potential for ecological risk from the pheromone use and from the growth-regulator uses is considered in this document. The ecological risk assessment identifies no ecological risks of concern from the use of aliphatic alcohols.

The risk assessments, which are summarized below, are based on the review of the required target database supporting the use patterns of currently registered products. After considering the potential risks identified, EPA has determined that aliphatic alcohol-containing products are eligible for reregistration. That decision is discussed fully in this document.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or “the Agency”). Reregistration involves a thorough review of the scientific database underlying a pesticide’s registration. The purpose of the Agency’s review is to reassess the potential risks arising from the currently registered uses of the pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the “no unreasonable adverse effects” criterion of FIFRA.

This document summarizes EPA’s human health and ecological risk assessments and reregistration eligibility decision (RED) for aliphatic alcohols. The document consists of six sections. Section I contains the regulatory framework for reregistration; Section II provides an overview of the chemical and a profile of its use and usage; Section III gives an overview of the human health and environmental effects risk assessments; Section IV presents the Agency's decision on reregistration eligibility and risk management; and Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Finally, the Appendices list related information, supporting documents, and studies evaluated for the reregistration decision. The risk assessments for aliphatic alcohols and all other supporting documents are available in the Office of Pesticide Programs (OPP) public docket (http://www.regulations.gov) under docket number EPA-HQ-OPP-2007-0134.

II. Chemical Overview

A. Regulatory History

Reregistration case number 4004 consists of straight chain aliphatic alcohols with 6 to 16 carbon atoms in the chain, which has been abbreviated in previous documents as aliphatic alcohols (Cx-Cxx) or (C6-C16). Currently, case 4004 consists of four active ingredients. Three of these active ingredients are used as plant growth regulators on tobacco. These are described as fatty alcohol blend (PC code 079029), 1-octanol (079037) and 1-decanol (079038). The fatty alcohol blend under PC code 079029 is predominantly a mixture of 1-octanol and 1-decanol, although some labels list 0.5% 1-hexanol (C6) and 1.5 % dodecanol (C12) among the active ingredients. The single product listed under PC code 079037, although listed as 1-octanol, is also in fact a mixture of 1-octanol and 1-decanol. The earliest registered label for use of aliphatic alcohols for tobacco sucker control included in the Agency’s Pesticide Product Label System (PPLS) was issued to Uniroyal in 1964.

The fourth active ingredient in case 4004, 1-dodecanol (PC code 001509), was first registered for use as a Lepidopteran pheromone/sex attractant in 1993. The potential human health risks from 1-dodecanol were reassessed in 2002 by the Agency's Biopesticides and Pollution Prevention Division (BPPD), as described in the document, *Tolerance Reassessment Decision Regarding Tolerance Exemption for the Biochemical Lepidopteran Pheromones. July 26, 2002.* This RED document describes the potential ecological effects of the use of 1-dodecanol.

Other aliphatic alcohols are not assessed in this document. The fatty alcohol product included under PC code 079059 is not being supported, and will be voluntarily cancelled. In April 1995, the Agency completed a Reregistration Eligibility Decision (RED) for case number 4003 (C1 - C5), which consists of aliphatic alcohols with only one to five carbons. The active ingredients addressed in that assessment included ethanol (PC code 001501), and isopropanol (PC code 047501).

B. Chemical Identification

The aliphatic alcohols are considered primary alcohols (i.e., the –OH group in the C-1 position). The aliphatic alcohols 1-octanol (PC code 079037) and 1-decanol (PC code 079038) are also known by many other common names, and the fatty alcohol blend (PC code 079029) is a generic term meaning that the compound is obtained by the hydrolysis of fatty acid esters. The registrations under the name fatty alcohol blend (PC code 079029) are considered a mixture of the linear, straight chain chemicals 1-octanol and 1-decanol. Tables 1 - 3 provide the chemical identification for 1-octanol, 1-decanol, and 1-dodecanol, respectively.

Table 1. Chemical Identification of 1-Octanol

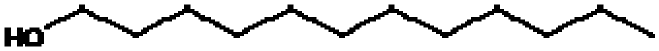
Type of Information	**Information for this Chemical**
IUPAC Name	**1-Octanol**
CAS Reg. No.	111-87-5
Other Names	Octyl alcohol; n-Octan-1-ol; n-Octanol; n-Octyl alcohol; Caprylic alcohol; Heptyl carbinol; Octanol; Alcohol C-8; Capryl alcohol; n-Heptyl carbinol; Octan-1-ol; Prim-n-octyl alcohol; Octanol-(1); Octyl alcohol, normal-primary; Primary octyl alcohol; Hydroxyoctane
Empirical Formula	$C_8H_{18}O$
Molecular Weight Number of Carbons	130.23 The number of carbons is 8
Chemical Structure	

Table 2. Chemical Identification of 1-Decanol

Type of Information	**Information for this Chemical**
IUPAC Name	**1-Decanol**
CAS Reg. No.	112-30-1
Other Names	Decyl alcohol; n-Decan-1-ol; n-Decanol; n-Decyl alcohol; Alcohol C10; Capric alcohol; Caprinic alcohol; Decanol; Nonylcarbinol; Decylic Alcohol; Decan-1-ol; Decanol-(1); Decyl, n- alcohol 22; Primary decyl alcohol; Nonyl carbinol
Empirical Formula	$C_{10}H_{22}O$
Molecular Weight Number of Carbons	158.28 The number of carbons is 10

Chemical Structure	

Table 3. Chemical Identification of 1-Dodecanol

Type of Information	Information for this Chemical
IUPAC Name	**1-Dodecanol**
CAS Reg. No.	112-53-8
Other Names	Dodecyl alcohol; *n*-Dodecan-1-ol; *n*-Dodecyl alcohol; Alcohol C-12; Dodecanol-1; Lauric Alcohol; Laurinic alcohol; Lauryl alcohol; 1-Dodecyl alcohol; Duodecyl alcohol; *n*-Lauryl alcohol; *n*-Lauric alcohol, primary; Dodecanol; 1-Hydroxydodecane; Hydroxydodecane
Empirical Formula	$C_8H_{18}O$
Molecular Weight Number of Carbons	186.33 The number of carbons is 12
Chemical Structure	

The aliphatic alcohols 1-octanol and 1-decanol are applied as water-based sprays to burley, flue cured and dark tobacco by hand using a back pack sprayer, or to tobacco plants by a boom. The aliphatic alcohols are applied to tobacco at the button or early flower stage and act as chemical pinching agents to control sucker shoots. The aliphatic alcohols dissolve the layer of waxy cuticle on the plant, causing dehydration of the young sucker. Because these aliphatic alcohols are applied solely on tobacco, its use is limited to the tobacco growing states, mainly on the east coast (Connecticut, Pennsylvania, Virginia, North Carolina, South Carolina, Georgia, and Florida), but also in Kentucky and Tennessee. Between 1.5 and 2 million pounds of aliphatic alcohols are applied annually.

Recommended application rates range from approximately 8.5 lbs ai/acre up to approximately 21 lbs active ingredient/acre, at 1 to 3 applications per year. However, 1-octanol and 1-decanol have estimated volatilization half-lives of 3.5 and 1.0 minutes, respectively.
Therefore, the amount of the aliphatic alcohol available for runoff or for chronic exposure to terrestrial animals is likely to be lower than the maximum label rates. As described below, the ecological risk assessment took this into account when estimating potential exposure.

The volatility of 1-dodecanol is essential to its use as a pheromone in apple and pear orchards. The pheromone is applied from polyethylene dispenser tubes hung throughout the orchard. The active ingredient, 1-dodecanol (lauryl alcohols; PC code 001509), disperses passively from the tube into the atmosphere over 3-4 months. Once dispersed from its dispensers, 1-dodecanol degrades quickly by photolysis in the air.

The aliphatic alcohols are used in, or can be naturally found in various food items. The Food and Drug Administration permits the use of aliphatic alcohols as a food additive, under certain conditions. The aliphatic alcohols have been found to be natural components of apples and oranges, and have been reported as a component of edible seeds, oils and fermented beverages.

III. Summary of Aliphatic Alcohols Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessment documents, and supporting information listed in Appendix C were used to formulate the safety finding and regulatory decision for aliphatic alcohols.

While the following risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket, docket number EPA-HQ-OPP-2007- 0134, and may also be accessed through the website http://www.regulations.gov/. Hard copies of these documents may be found in the OPP public docket under this same docket number.

- *Tolerance Reassessment Decision Regarding Tolerance Exemption for the Biochemical Lepidopteran Pheromones. July 26, 2002;*
- Human Health Risk Assessment: *Aliphatic Alcohols: Human Health Chapter of the Reregistration Eligibility Decision (RED) Document. Reregistration Case Number 4004. June 30, 2006;*
- Ecological Risk Assessment: *Reregistration Eligibility Decision, Reregistration Case 4004: Aliphatic Alcohols C-8, C-10 and C-12. September 8, 2006.*
- *Aliphatic Alcohols (1-octanol; 1-decanol): Tier 2 Aquatic Exposure Model (PRZM and EXAMS) Estimates and Risk Characterization. November 28, 2006;*
- *Aliphatic Alcohols (1-octanol; 1-decanol): Addendum to PRZM and EXAMS refinement of environmental concentrations in surface water (DPBarcode D334066; 11/28/2006). Recalculation of EECs considering volatilization from soil as a dissipation route; Recalculation of Risk Quotients. December 11, 2006;*
- *Aliphatic Alcohols (1-octanol; 1-decanol) Addendum to Ecological Risk Assessment in Support of RED: Reconsideration of Ecological Toxicity Data Gaps in Light of Surface Water EEC Refinements. February 9, 2007.*

A. Human Health Risk Assessment

The Agency has conducted a risk assessment of the tobacco plant growth inhibitor use of the aliphatic alcohols. The Agency's screening level assessment was conducted using data submitted by the registrants and published in the open literature. A summary of the Agency's human health risk assessment is presented below. More detailed information associated with the risks posed by the tobacco plant growth inhibitor use of the aliphatic alcohols can be found in the human health risk assessment, *Aliphatic Alcohols: Human Health Chapter of the Reregistration Eligibility Decision (RED) Document. Reregistration Case Number 4004*, which is available in the public docket.

The potential human health risks from 1-dodecanol were assessed in 2002 by the Agency's Biopesticides and Pollution Prevention Division (BPPD), as described in the document, *Tolerance Reassessment Decision Regarding Tolerance Exemption for the Biochemical Lepidopteran Pheromones. July 26, 2002.* The tolerance exemption for Lepidopteran pheromones, including 1-dodecanol, was determined to be in compliance with FQPA.

Toxicity Summary for Aliphatic Alcohols

The data base of submitted toxicity studies and published literature is sufficient to assess the uses of the aliphatic alcohols. The available toxicity data base for the aliphatic alcohols consists of acute toxicity, irritation, and sensitization studies. In addition, there are developmental rat (oral and inhalation) toxicity studies and a 90-day rat (dermal) study. The available mutagenicity studies include the Ames, micronucleus, and gene mutation assays.

Currently, there is no known mode of toxicological action for the aliphatic alcohols. Based on the low hazard concern via the oral, dermal, and inhalation routes of exposure, a quantitative risk assessment for the aliphatic alcohols is not appropriate. Therefore, the Agency conducted a qualitative assessment.

Toxicity Profile

Available acute toxicity studies indicate the aliphatic alcohols are of low oral and dermal toxicity. Acute inhalation studies with the rat resulted in estimates of the median lethal dose (LD_{50}) above the limit concentration of 2 mg/L. However, eye irritation studies resulted in severe and sometimes non-reversible eye irritation. Dermal irritation studies revealed slight to moderate irritation in rabbits, and the aliphatic alcohols generally did not produce sensitization in tests with guinea pigs.

There are few subchronic or chronic toxicity data available for the aliphatic alcohols; however, the available developmental toxicity studies revealed no adverse effects in fetal and maternal parameters. The available genotoxicity and mutagenicity studies were negative. There is currently no long-term rodent toxicity information regarding the carcinogenic potential for the aliphatic alcohols. While neurotoxicity information is currently not available, there were no clinical signs in any of the acute, subchronic, or developmental toxicity studies to suggest the aliphatic alcohols elicit a neurotoxic effect. Based on the available data, there is no evidence that warrants determining any dietary, oral, dermal, or inhalation endpoints to quantify sub-chronic or chronic toxicity.

Finally, there is no evidence to suggest that the aliphatic alcohols cause increased susceptibility in infants and children. Therefore, based on the results of the available studies, no endpoints of toxicological concern have been identified for human health risk assessment purposes. Table 4 summarizes the available toxicity data for the aliphatic alcohols.

Table 4. Acute Toxicity Data for the Aliphatic Alcohols

Guideline No.	Study Type	PC Code	MRID	Results	Toxicity Category
870.1100 81-1	Acute oral [rat]	079038 1-Decanol	44460401 46004601	LD_{50} > 2000 mg/kg (other studies report no deaths at 2000 mg/kg, one study showed LD_{50}	III
			45507901 0060309 0064859	=5000 mg/kg)	

870.1200 81-2	Acute dermal [rat]	079038 1-Decanol	44460402 46004602 45507902	LD_{50} reported as > 2000 mg/kg; (other studies reported LD_{50}> 4000 mg/kg and one study showed LD_{50} = 5000 mg/kg	III
870.1300 81-3	Acute inhalation [rat]	079038 1-Decanol	44460403 46004603 45517901	LD_{50}> 3.35 mg/L (other studies showed LD_{50}>5.07 mg/L and LD_{50}>7.08 mg/L)	IV
870.2400 81-4	Acute eye irritation [rabbit]	079038 1-Decanol	44460404 44578801 46004604 45517902	Most severe effect reported as corneal opacity in all treated eye at 7 days. Conjunctive irritation until 7 and 14 days. Irreversible vascularisation in one eye until day 21	I-III
870.2400 81-4	Acute eye irritation [rabbit]	079029 Fatty Alcohols	44340701	All 6 rabbits showed moderate to severe irritation. Opacity up to 7 days. Slight iritis with conjunctival redness to day 6, slight chemosis to day 7 and slight to severe discharge to day 8.	II-III
870.2500 81-5	Acute dermal irritation [rabbit]	079038 1-Decanol	44407601 44460405 46004605 45517903	In one study, erythema, eschar formation and edema was evident at 72 hrs. Test substance reported as mild irritant.	III-IV
870.2600 81-6	Skin sensitization [guinea pig]	079038 1-Decanol	44407602 44460406 46004606 45507903	Three studies reported 1-decanol is not a skin sensitizer.	NA
870.2600 81-6	Skin sensitization [guinea pig]	079029 Fatty Alcohols	43386201	All animals survived. No adverse effect on body weight. Not a dermal sensitizer.	NA

B. Environmental Risk Assessment

The Agency has conducted a screening-level risk assessment of the tobacco plant growth inhibitor and pheromone uses of the aliphatic alcohols. The Agency's screening level assessment was conducted using data submitted by the registrants in conjunction with acceptable ecotoxicity data from the open literature. Anticipated exposure pathways to non-target species include oral exposure, and inhalation of aliphatic alcohol products.

A summary of the Agency's ecological risk assessment is presented below. More detailed information associated with the ecological risks posed by use of the aliphatic alcohols can be found in the environmental risk assessment, *Reregistration Eligibility Decision for the Aliphatic Alcohols*, dated September 8, 2006, which is available in the public docket.

1. Environmental Fate and Transport

Because environmental fate data are not available, physical and chemical properties for the aliphatic alcohols were estimated by Quantitative Structure-Activity Relationships (QSAR) using EPISuite v3.21 (Estimation Programs Interface for Windows (EPIWIN)). The estimated properties of 1-octanol, 1-decanol and 1-dodecanol differ somewhat, due to the different lengths (i.e. number of carbons) in their straight, saturated carbon chains. As suggested by their common names, 1-octanol has 8 carbons in its chain, 1-decanol has 10 carbons, and 1-dodecanol has 12 carbons.

In spite of these small differences, the expected behavior of these aliphatic alcohols in the environment is generally similar. The major route of dissipation in the field for these chemicals is likely to be volatilization. The volatility half-lives for 1-octanol and 1-decanol were estimated using the Dow Method described in the *Handbook of Chemical Property Estimation Methods* by Lyman, Reehl and Rosenblatt. The half-lives for volatility from soil for 1-octanol and 1-decanol were estimated to be 3.5 minutes and 1 minute, respectively. 1-dodecanol would likely volatilize even more quickly, but the half-life was not estimated, since volatility from pheromone traps is the known route of dissipation.

There is some uncertainty about the rate of volatility of 1-octanol and 1-decanol from plant surfaces, since aliphatic alcohols are hydrophobic and, therefore, have affinity for the waxy surfaces of plants. However, these volatility half-lives suggest that the aliphatic alcohols will not be available long to expose non-target terrestrial animals, nor to be transported to surface water bodies in runoff. Residues of 1-dodecanol are not expected on plants or in soil, since they are dispersed in the air from pheromone traps, and then degraded by photolysis. The ecological risk assessment concluded that except for terrestrial insects, which are the target for the pheromone use of 1-dodecanol, “environmental exposures resulting from this use are likely negligible.” The risk assessment for this use was therefore qualitative.

Additional estimation of environmental fate parameters obtained from EPISuite provides a basic set of data to perform a screening-level environmental risk assessment. The model indicates that aliphatic alcohols have a moderate tendency to bind to soils. The portion of applied chemical that binds to the soil, rather than volatilizing, will be subject to biodegradation, with estimated half-lives for 1-octanol and 1-decanol of 2.3 days. The portion of applied chemical that does volatilize is estimated to degrade in the air by reaction with hydroxyl radicals with half-lives of about 10 hours.

As mentioned above, dissipation via volatilization will greatly reduce the amount of aliphatic alcohols reaching surface-water bodies, and aliphatic alcohols will volatilize from water as well as soil. However, the fraction that does reach surface water will not be degraded by hydrolysis. These alcohols have the potential to bioaccumulate in fish, but the rates of uptake, metabolism, and depuration, as well as the nature of metabolites, are not known. However, the magnitude of the bioconcentration factors (BCF) suggests a low potential to bioconcentrate.

EPISuite does not provide information on the rates of formation/decline of product, the nature and relative amounts of transformation products, and their distribution in soil/sediment-water-air. Therefore, the specific nature and persistence of potential biotransformation products (primary biodegradation) are not known. However, the ultimate biotransformation products of the aliphatic alcohols are water and carbon dioxide.

2. Ecological Risk Assessment

The Agency uses a pesticide's use profile, exposure data, and toxicity information to determine risk estimates to non-target terrestrial and aquatic organisms. Estimated environmental concentrations (EECs) are used to calculate risk quotients (RQs). EECs are based on the maximum application rate(s) which would potentially yield the greatest exposure. An RQ is derived by dividing the EEC by a single estimate of toxicity. The Agency then compares an RQ to its Level of Concern (LOC) to determine if exposure to the aliphatic alcohols could potentially pose a risk to non-target organisms (RQs that exceed the LOC indicate potential risk). Table 5 outlines LOCs, and the Agency's corresponding risk presumptions.

Table 5. Agency Level of Concerns and Risk Presumptions Risk Presumption	LOC Terrestrial Animals	LOC Aquatic Animals	LOC Plants
Acute Risk – there is a potential for acute risk	0.5	0.5	1
Acute Endangered Species – endangered species may be adversely affected	0.1	0.05	1
Chronic Risk – there is potential for chronic risk	1	1	N/A

a. Exposure to Aquatic Organisms

The Agency ran a number of exposure modeling simulations to derive expected environmental concentrations of aliphatic alcohols in surface water. The Agency first ran the Tier I GENEEC model, which resulted in exceedences of the endangered species level of concern (LOC) for freshwater fish and estuarine/marine invertebrates for some application scenarios. However, these simulations did not consider the volatilization of aliphatic alcohols from soil, and each thereby overestimated potential exposure.

Although GENEEC is not designed to consider volatility from soil directly, the Agency used an indirect method to consider volatility with the GENEEC model and to refine the aquatic exposure assessment. As described above, the volatility half-lives for the aliphatic alcohols were estimated using the Dow Method described in the *Handbook of Chemical Property Estimation Methods* (Lyman, et al., 1982). The half-lives for volatility from soil for 1-octanol and 1-decanol were estimated to be 3.5 minutes and 1 minute, respectively. Such short volatility half-lives mean that little pesticide will remain by the time a runoff event occurred, unless rainfall began immediately after application.

To simulate this scenario using GENEEC, the Agency determined the amount of 1-octanol or 1-decanol that would remain in the field 3 to 4 minutes after application at the maximum rates allowed on the label. GENEEC was then run in the standard fashion, but with this "effective application rate." Even though this was done using estimated volatility half-lives on the order of a couple of minutes, the resulting EECs are still considered upper-bound. GENEEC does not simulate a rainfall event until two days after application; if rainfall does not occur until two days after actual application of 1-octanol or 1-decanol, there could be very little product remaining to be subject to transport in runoff. For this reason, the simulations considered only a single application, although aliphatic alcohols can be used more than once within a single growing season.

b. Toxicity to Aquatic Organisms

Registrant-submitted data and open literature studies suggest that the aliphatic alcohols are "slightly" to "moderately" toxic to freshwater fish. Although the data base is not complete for all compounds in the aliphatic alcohol registration case, there are adequate data to assess the acute risk to freshwater fish. Although there are no registrant-submitted acute toxicity data available for estuarine/marine fish, data from the open literature provided the information to assess the acute risks of aliphatic alcohols to these organisms. The relevant study from the open literature indicates that 1-octanol is "slightly" toxic, and 1-decanol is "moderately" toxic to estuarine/marine fish.

No chronic toxicity guideline studies exist for any of the aliphatic alcohols. However, chronic data for freshwater fish from the open literature on 1-octanol provide an endpoint which the Agency used to calculate RQs. Chronic toxicity data for aquatic invertebrates on the aliphatic alcohols were also drawn from the open literature. The Agency used a chronic no
observed adverse effect concentration (NOAEC) of 1 mg/L for reproductive effects for 1-octanol. The Agency notes that chronic toxicity data on 1-decanol for aquatic invertebrates would reduce the uncertainty posed by the lack of these data. A summary of all toxicity endpoints is presented below in Table 6.

Table 6. Toxicity Reference Values Used to Calculate RQs for Aliphatic Alcohols

Taxonomic Group	**Assessment Endpoint**	**1-Octanol**	**1-Decanol**
		Species/ Toxicity Endpoint	**Species/ Toxicity Endpoint**
Freshwater Fish	Survival	Fathead minnow Acute LC_{50} = 12.2 mg/L	Fathead minnow Acute LC_{50} = 2.3 mg/L
	Reproduction, Growth	Fathead minnow NOAEC = 0.75 mg/L	
Taxonomic Group	**Assessment Endpoint**		
		Species/ Toxicity Endpoint	**Species/ Toxicity Endpoint**
Freshwater Invertebrates	Survival	Water flea Acute EC_{50} = 4.16 mg/L	Water flea Acute EC_{50} = 6.5 mg/L
	Reproduction, Growth	Water flea Chronic NOAEC = 1 mg/L	No data available
Estuarine/marine Fish	Survival	Bleak LC_{50} = 15 mg/L	Bleak LC_{50} = 7.2 mg/L
	Reproduction, Growth	No data available	No data available
	Survival	Harpacticoid copepod LC_{50} = 58 mg/L	Harpacticoid copepod LC_{50} = 4 mg/L

Estuarine/marine Invertebrates	Reproduction, Growth	No data available	No data available
Aquatic Plants	Survival, Growth	*Scenedesmus subspicatus* EC$_{50}$ = 6.5 mg/L; EC$_{10}$ = 2.8 mg/L	No data available

LC$_{50}$ - Median Lethal Concentration, statistically derived single concentration that can be expected to cause death in 50% of the test animals; EC$_{50}$ - Median Effect Concentration, statistically derived single concentration that can be expected to cause an adverse effect in 50% of the test animals or plants; EC$_{10}$ - statistically derived single concentration that can be expected to cause an adverse effect in 10% of the test animals or plants; NOAEC - no observed adverse effect concentration.

c. Risk to Aquatic Organisms

Based on the refined surface water EECs and the available ecotoxicity data for 1-octanol and 1-decanol, RQs for aquatic animals do not exceed acute LOCs. In addition, although chronic toxicity data are available for 1-octanol, but not 1-decanol, aliphatic alcohols do not appear to pose a chronic risk to freshwater aquatic animals. No chronic toxicity data are available for estuarine/marine fish and invertebrates. In spite of these data gaps, the Agency does not anticipate chronic risk to estuarine marine fish and invertebrates. As described above, little 1- octanol or 1-decanol would likely be available for transport in runoff if a significant rain event did not occur within a few hours of application. Estimated RQs for 1-decanol and 1-octanol are Estimated RQs for 1-decanol and 1-octanol are summarized in Tables 7 – 10 below.

Table 7. Acute and Chronic RQs for Freshwater Fish

Chemical	Effective Application Rate (lbs a.i./acre)	Peak EEC (μg/L)	Toxicity Value (μg/L)	Acute RQ	60-Max Average EEC (μg/L)	Chronic RQ
1-Decanol	1.95, 1 application	57	LC$_{50}$ = 2300 NOAEC – nd	0.02	13	nd
1-Octanol	4.4, 1 application	140	LC$_{50}$ = 12200 NOAEC = 750	0.01	29	<1

Table 8. Acute and Chronic RQs for Estuarine/Marine Fish

Chemical	Effective Application Rate (lbs a.i./acre)	Peak EEC (μg/L)	Toxicity Value (μg/L)	Acute RQ	60-Max Average EEC (μg/L)	Chronic RQ
1-Decanol	1.95, 1 application	57	LC$_{50}$ = 7200 NOAEC – nd	<0.01	13	nd
1-Octanol	4.4, 1 application	140	LC$_{50}$ = 15000 NOAEC – nd	<0.01	29	nd

Table 9. Acute and Chronic RQs for Freshwater Invertebrates

Chemical	Effective Application Rate (lbs a.i./acre)	Peak EEC (µg/L)	Toxicity Value (µg/L)	Acute RQ	21-Max Average EEC (µg/L)	Chronic RQ
1-Decanol	1.95, 1 application	57	EC_{50} = 6500 NOAEC – nd	<0.01	29	nd
1-Octanol	4.4, 1 application	140	EC_{50} = 4160 NOAEC = 1000	0.03	70	<1

Table 10. Acute and Chronic RQs for Estuarine/Marine Invertebrates

Chemical	Effective Application Rate (lbs a.i./acre)	Peak EEC (µg/L)	Toxicity Value (µg/L)	Acute RQ	21-Max Average EEC (µg/L)	Chronic RQ
1-Decanol	1.95, 1 application	57	EC_{50} = 4000 NOAEC – nd	0.01	29	nd
1-Octanol	4.4, 1 application	140	EC_{50} = 58000 NOAEC – nd	<0.01	70	nd

nd = no data

Aquatic plant toxicity data from open literature were only available for 1-octanol. Based on these data, the acute RQs for aquatic plants do not exceed the Agency's acute and endangered species LOCs (both 1.0) (Table 11). However, there is some uncertainty in this risk conclusion, given that the NOAEC for 1-octanol is unknown, and no aquatic phytotoxicity data are available for 1-decanol. The NOAEC is used to calculate an RQ to evaluate potential risk to endangered species. Because the NOAEC was not established, the EC_{10} for 1-octanol was used. Since the LOC for endangered aquatic plants is 1.0, and the RQ derived using the EC_{10} is 0.05, the NOAEC would have to be at least 20 times lower than the EC_{10} for the Agency to have an endangered species concern for aquatic plants.

Based on the analysis of the volatility of the aliphatic alcohols, aquatic exposures resulting from the labeled use of 1-decanol and 1-octanol are unlikely to reach concentrations that exceed the Agency's LOC. As a result, the value of additional aquatic plant studies for the aliphatic alcohols is low.

Table 11. Risk to Aquatic Plants

Chemical	Rate (lbs a.i./acre)	Peak EEC (µg/L)	Toxicity Value (µg/L)	Acute RQ
1-Octanol	4.4, 1 application	140	EC_{50} = 6500 EC_{10} = 2800	0.02 0.05
1-Decanol	1.95, 1 application	57	No data	--

d. Exposure, Toxicity and Risk to Terrestrial Organisms

Birds

Available toxicity data indicate that the aliphatic alcohols are categorized as “practically non-toxic” to birds on acute oral and dietary bases. Acute risks to birds were not quantified, because no discreet median lethal doses or concentrations were established in the acute oral and dietary studies. An acute dietary study from the open literature reported a dietary LC_{50} for bantam chickens of 201,000 ppm (100% 1-decanol). This level is more than 20 times greater than the highest predicted dietary exposure level (~10,000 ppm). Therefore, the Agency concludes that the aliphatic alcohols do not pose an acute risk to birds.

No avian chronic toxicity studies were available for any of the aliphatic alcohols and, therefore, the Agency cannot directly assess the potential chronic risk to avian species. However, since 1) the aliphatic alcohols are not acutely toxic to birds at doses many times higher than expected exposure, 2) the volatility of the aliphatic alcohols makes chronic exposure unlikely, with EECs dropping more than an order of magnitude within 30 minutes, 3) the aliphatic alcohols assessed are listed as food additives and are “Generally Recognized as Safe” (GRAS) by the U.S. Food and Drug Administration1, and 4) a mammalian chronic toxicity study indicates the aliphatic alcohols are not chronically toxic to mammals, the Agency does not expect a chronic risk to birds, and will not require chronic avian toxicity studies at this time.

Mammals

Acute oral mammalian toxicity data indicate that the aliphatic alcohols are “practically non-toxic” to mammals on an acute oral basis. Four studies performed with laboratory rats did not result in LC_{50} endpoints with which RQs could be calculated. The Agency concludes that aliphatic alcohols do not pose an acute dietary risk to mammals.

In the single chronic mammalian developmental toxicity study, which used a 1-decanol/1-octanol blend, no chronic effects were observed in laboratory rats, even at the maximum tested dose of 957 mg/kg bw/day. It is unknown if the predicted exposures approach the level at which effects may occur since no LOAEC was identified in the chronic study. However, the Agency does not anticipate chronic risk to mammals, considering the volatility of the aliphatic alcohols, and the acceptance of these chemicals as food additives, as described above.

Terrestrial Insects

Available toxicity data indicate that aliphatic alcohols are “practically non-toxic” to honey bees (acute contact $LD_{50} > 25$ μg/bee). However, given that aliphatic alcohols can be used as Lepidopteran sex inhibitors, there is a potential for sublethal (e.g., reproductive) effects on non-target Lepidopterans, such as butterflies. This potential effect cannot be quantified at this time.

Terrestrial Plants

Tier-I terrestrial plant seedling emergence study data suggest a fatty alcohol blend (1- decanol and 1-octanol) is not toxic to most plants at the maximum rate tested (18.03 lbs ai/A). An EC_{25} could not be established for tested species, although lesser effects were observed in cucumbers, carrots and tomatoes. Therefore, the Agency did not calculate RQs based on seedling emergence effects.

EC_{25} values and related no-effect levels were established for two (corn and cucumber) of 10 crop plants tested in a submitted vegetative vigor study. The Agency used these endpoints in the TerrPlant model to calculate RQs (Table 12). All were below the Agency’s LOC of 1.

Table 12. Terrestrial Plant Vegetative Vigor RQs from Drift only for Terrestrial Plants*

Class of Terrestrial Plant	Monocot	Dicot
Non-endangered species	0.02	0.01
Endangered species	0.19	0.36
* Based on vegetative vigor monocot NOAEL = 1.12 lbs a.i./A, EC25 = 9.02 lbs a.i./A; dicot NOAEL = 0.58 lbs a.i./A, EC25 = 14.8 lbs a.i./A (MRIDs 42514701, 43379602)		

e. Adverse Ecological Incidents

There are currently no adverse ecological incidents listed in the Ecological Incident Information System (EIIS) that are associated with the aliphatic alcohols.

f. Endangered Species

Based upon the screening-level assessment conducted on aliphatic alcohols, the Agency has not definitively identified exceedences of endangered species LOCs for direct effects to non- target animals or plants. Acute RQs did not exceed endangered species LOCs for birds, mammals, terrestrial plants, freshwater fish and invertebrates, or estuarine/marine fish and invertebrates. Chronic data were not available for birds and estuarine/marine fish and invertebrates. As described above, the Agency believes that the volatility and low toxicity in available acute and chronic toxicity studies for mammals and freshwater animals suggest that chronic risk to birds and estuarine/marine animals is unlikely. However, because the toxicity data are not available, the Agency cannot completely preclude risk to listed birds and estuarine/marine animals at this time. Similarly, since a no-effect level was not determined for aquatic plants, the Agency cannot preclude direct effects on these organisms, although exposure is expected to be negligible.

The Agency considers a potential for not only direct effects, but also adverse indirect effects to listed species that rely on other affected organisms. Because direct effects to aquatic plants cannot be precluded, indirect effects to listed aquatic species which rely on aquatic plants can also not be dismissed. Similarly, indirect effects to terrestrial plants and animals cannot be precluded because of potential reproductive effects of aliphatic alcohols to some terrestrial insects.

Table 13. Potential Listed Species Risks Associated with Direct or Indirect Effects Due to Applications of Aliphatic Alcohols as Shoot Inhibitors on Tobacco.

Listed Taxon	Direct Effects		Indirect Effects to Endangered Species
	Acute	**Chronic**	
Terrestrial and semi-aquatic plants - monocots	No	N/A	Possible
Terrestrial and semi-aquatic plants - dicots	No	N/A	Possible
Birds	No	No data	Possible
Terrestrial-phase amphibians	No	No data	Possible
Reptiles	No	No data	Possible
Mammals	No	No	Possible
Aquatic non-vascular plants*	Insufficient data	N/A	N/A

Aquatic vascular plants	Insufficient data	N/A	N/A
Freshwater fish	No	No	Possible
Aquatic-phase amphibians	No	No	Possible
Freshwater crustaceans	No	No	Possible
Mollusks	No	N/A	Possible
Marine/estuarine fish	No	No data	Possible
Marine/estuarine crustaceans	No	No data	Possible

* At the present time, no aquatic non-vascular plants are included in Federal listings of threatened and endangered species. The taxonomic group is included here for the purposes of evaluating potential contributions to indirect effects to other taxa and as a record of exceedences should future listings of non-vascular aquatic plants warrant additional evaluation of Federal actions.

Further analysis regarding the overlap of individual species with each use site is required prior to determining the likelihood of potential impact to listed species. At the screening level, this analysis is accomplished using the Location of Crops and Threatened and Endangered Species (LOCATES) data base, which uses location information for listed species at the county level and compares it to agricultural census data for crop production at the same county level of resolution. The ecological risk assessment includes a complete listing of aquatic plants, birds, reptiles, terrestrial-phase amphibians, mammals, and terrestrial invertebrates associated with the States where the aliphatic alcohols are use as a plant growth regulator on tobacco.

• Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing aliphatic alcohols as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing aliphatic alcohols (C6 – C16).

The Agency has completed its assessment of the human health and ecological risks associated with the use of pesticide products containing aliphatic alcohols (C6 – C16). The Agency has determined that aliphatic alcohol-containing products are eligible for reregistration provided that label amendments are made as outlined in Chapter V. Appendix A summarizes the uses of aliphatic alcohols (C6 – C16) that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of aliphatic alcohols (C6 – C16), and lists the submitted studies that the Agency found acceptable. The Agency has identified eye-irritation concerns that warrant specific label language concerning personal protective equipment (PPE) and the length of restricted-entry intervals after application for tobacco uses of the aliphatic alcohols (C6 – C16). If all changes outlined in this document are incorporated into the product labels, the eye-irritation concerns will have been mitigated. Should a registrant fail to implement any of the reregistration requirements identified in this document, the Agency may take regulatory action to address these concerns.

B. Public Comment Period

Because the risks associated with the use of aliphatic alcohols were low and did not warrant mitigation measures, a Phase 3 public comment period on the aliphatic alcohols risk assessments was not conducted. However, a 60-day public comment period will be conducted after the RED is issued, and will be announced in the Federal Register. Comments may be submitted under Docket number EPA-HQ-OPP-2007-0134 at http://www.regulations.gov/. The RED document and technical supporting documents for aliphatic alcohols are also available to the public under docket identification (ID) number EPA-HQ-OPP-2007-0134. In addition, the aliphatic alcohols RED document may be downloaded or viewed through the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

C. Regulatory Position

1. Regulatory Rationale

The Agency has determined that aliphatic alcohols-containing products are eligible for reregistration provided that specified label amendments are made. The following is a summary of the rationale for managing risks associated with the use of aliphatic alcohols.

a. Human Health Risk Management

There are no human health risk concerns for the aliphatic alcohols with the exception of eye irritation for 1-decanol. 1-decanol, which is a component of all active tobacco use formulations of the aliphatic alcohols (C6 – C16), is an acute toxicity category I eye irritant and, therefore, pursuant to the Worker Protection Standards (WPS), products with agricultural uses must require a 48 hour REI and the following PPE for early entry: coveralls, chemical-resistant gloves made of any water proof material, shoes plus socks, and protective eyewear.

b. Ecological Risk Management

The risk assessment identified no exposure scenarios with aliphatic alcohols that pose ecological risks of concern to the Agency, including direct effects on endangered species. Thus, no mitigation measures to address ecological risks are necessary for the reregistration of aliphatic alcohols.
Moreover, because of the low risks associated with the use of aliphatic alcohols, as summarized in this document, the Agency concludes that spray drift mitigation is not needed as part of the reregistration eligibility determination.

2. Endocrine Disruptor Effects

Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, individual pesticides may be subject to additional screening and/or testing. However, in the available toxicity studies for the aliphatic alcohols, there was no evidence of endocrine disruption.

3. Endangered Species

The Endangered Species Act required federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on federally listed endangered and threatened species, and to implement mitigation measures that address these impacts. To assess the potential of registered pesticide uses that may affect any particular species, EPA puts basic toxicity and exposure data developed for the REDs into context for individual listed species and considers ecological parameters, pesticide use information, the geographic relationship between specific pesticide uses and species locations and biological requirements and behavioral aspects of the particular species. When conducted, these analyses take into consideration any regulatory changes recommended in this RED being implemented at that time. A determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, and/or consultations with the Fish and Wildlife Service or National Marine Fisheries Service, as necessary. If the Agency determines use of aliphatic alcohols “may affect” listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402).

The ecological assessment that EPA conducted for this RED does not, in itself, constitute a determination as to whether specific species or critical habitat may be harmed by the pesticide. Rather, this assessment serves as a screen to determine the need for any species specific assessment that will evaluate whether exposure may be at levels that could cause harm to specific listed species and their critical habitat. That assessment refines the screening-level assessment to take into account the geographic area of pesticide use in relation to the listed species, the habits and habitat requirements of the listed species, etc. If the Agency’s specific assessments for aliphatic alcohols result in the need to modify use of the pesticide, any geographically specific changes to the pesticide’s registration will be implemented through the process described in the Agency’s Federal Register Notice (54 FR 27984) regarding implementation of the Endangered Species Protection Program.

The Agency has reviewed data and other information for the aliphatic alcohols (C6 – C16) and concludes that this plant growth regulator does not pose a risk of direct acute effects to most species listed under the Endangered Species Act, because EPA’s screening-level assessment shows ‘no effect’ on listed species or their critical habitat (RQ values were below the level of concern for endangered species). There is some uncertainty regarding acute risk to aquatic plants, however. Although the volatility of 1-octanol and 1-decanol suggests that exposure to aquatic plants would be negligible, a no-observed-adverse-effect-level could not be established and, therefore, indirect effects to listed aquatic animals which depend on aquatic plants could not be precluded. Similarly, the Agency believes that the volatility and low toxicity in available acute and chronic toxicity studies for mammals and freshwater animals suggest that chronic risk to birds and estuarine/marine animals is unlikely. However, because the toxicity data are not available, the Agency cannot completely preclude risk to listed birds and estuarine/marine animals at this time.

C. Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing aliphatic alcohols. For the specific labeling statements, refer to Section V of this RED document.

V. What Registrants Need to Do

The Agency has determined that aliphatic alcohols (C6 – C16)-containing products are eligible for reregistration provided that the required label amendments are made. The Agency intends to issue Data Call-In (DCIs) Notices requiring product-specific data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product-specific data, the registrant will have eight months to submit data. Below are the label amendments that the Agency intends to require for aliphatic alcohols to be eligible for reregistration.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of aliphatic alcohols for currently registered uses has been reviewed and determined to be substantially complete. However, a few data gaps remain, and these are listed below.

<u>Product Chemistry</u>

830.7050 UV/VIS Spectrum for Pure Active Ingredient (PAI)
830.7950 Vapor Pressure

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing-use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table 14.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements. For any questions regarding the PDCI, please contact Karen Jones at 703-308-8047.

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 15. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

Table 14: **Labeling Changes Summary Table for 1-Octanol, 1-Decanol and Fatty Alcohols**

Description	**1-Octanol, 1-Decanol and Fatty Alcohols : Required Labeling Language**		**Placement on Label**
	Manufacturing-Use Products		
Required on all MUPs	"Only for formulation into a growth regulator for tobacco sucker control."		Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group.	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."		Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."		Directions for Use

End-Use Products Intended for Occupational Use (WPS and non-WPS)			
Handler PPE Requirements[1] for (insert type of formulation) Note: Separate sections should be used for each formulation type (i.e. liquids, powders, granulars, etc…) unless the required handler PPE is identical for all formulation types.		"Personal Protective Equipment (PPE) Mixers, loaders, applicators, and other handlers must wear: > Long-sleeved shirt and long pants and, > Shoes plus socks"	Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements		"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing and other absorbent material that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
User Safety Recommendations		"USER SAFETY RECOMMENDATIONS" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box)

Environmental Hazards Statement	"ENVIRONMENTAL HAZARDS" Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of wastes."	Precautionary Statements under Environmental Hazards
Restricted-Entry Interval for products with WPS uses	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours."	Directions for Use, Agricultural Use Requirements Box
Early Entry Personal Protective Equipment for products with WPS uses	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as soil or water, is: > coveralls, > shoes plus socks, > chemical-resistant gloves made of any waterproof material, > protective eyewear."	Directions for Use, Agricultural Use Requirements Box
General Application Restrictions for products with WPS or non-WPS uses on the label	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift." "Only protected handlers may be in the area during application."	Place in the Direction for Use.

1
PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. In the case of multiple active ingredients, the more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

APPENDIX A

R.E.D. FACTS

Aliphatic Alcohols

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 4003, aliphatic alcohols, which contains the active ingredients ethanol and isopropanol.

Use Profile

Aliphatic alcohols are registered for uses which include hard surface treatment disinfectants, sanitizers, a sterilant, virucides, fungicides, and mildewcides. Ethanol also is registered for use as a plant growth regulator (a ripener), and is used with quaternary ammonium compounds in swimming pool water systems. Isopropanol also is used in combination with other pesticide active ingredients to kill fleas, ticks, and other household insects. Both ethanol and isopropanol are well known substances and have a wide range of human uses. For example, ethanol is contained in some beverages, and isopropanol is the major ingredient in rubbing alcohol.

Aliphatic alcohols are applied as surface wipes, sprays, mop-on, sponge-on, wipe-on or pour-on treatments, by immersion, and through closed systems (for commercial/industrial water cooling systems).

Use practice limitations for ethanol include cautions not to use the product on polished wood furniture or rayon fabrics, and not to get the product on foods, drinks, feeds, or surfaces they may contact. Isopropanol is not recommended for use on aluminum, should not be used on polished wood furniture or rayon fabrics, and should not be sprayed on lacquered or shellacked surfaces. Used solution should not be poured back into the bottle.

Regulatory History

Aliphatic alcohols were first registered as indoor disinfectants in the U.S. as early as 1948. Currently, 73 ethanol and 67 isopropanol pesticide products are registered. Ethanol and isopropanol are considered inert ingredients in some pesticide formulations; a determination is made on a case-by-case basis.

Historically, aliphatic alcohols have been regulated both as pesticides under EPA's jurisdiction and as devices under the Food and Drug Administration (FDA)'s purview. This regulatory burden has been reduced by a 1993/94 Memorandum of Understanding (MOU) which divides liquid chemical germicides into two categories: sterilants (which FDA will regulate) and general purpose disinfectants (which EPA will regulate). Both Agencies will continue to have jurisdiction over all liquid chemical germicides until rulemaking has been completed, but product performance and efficacy data need only be reviewed by the Agency with primary jurisdiction.

The case aliphatic alcohols contain three other active ingredients--methanol, propyl alcohol, and tert-butyl alcohol--which are not being supported for reregistration.

Human Health Assessment

Toxicity

In studies using laboratory animals, aliphatic alcohols have been shown to be of low acute toxicity. Ethanol has been placed in Toxicity Category IV (indicating the lowest degree of acute toxicity) for all effects tested including acute oral and inhalation toxicity, and primary eye and skin irritation. Isopropanol also has been placed in Toxicity Category IV for all effects except acute oral toxicity, for which it is placed in Toxicity Category III. In an acute neurotoxicity study using rats, isopropanol vapors caused decreased motor activity and effects on nervous system functions at the higher dose levels.

In a subchronic toxicity study using rats, ethanol caused decreased body weights and fatty degeneration in the livers of treated animals. In a study using human volunteers, ethanol-saturated patches caused skin irritation at 19-21 days of exposure. An inhalation study using rats, guinea pigs, rabbits, monkeys, and dogs resulted in no signs of toxicity.

In a subchronic inhalation study using rats and mice, isopropanol caused some clinical signs including ataxia, narcosis, hypoactivity, and lack of startle response, as well as kidney lesions. In a subchronic inhalation study using rats, no treatment-related changes were noted but motor activity was increased at the highest dose level.

In a chronic toxicity study using rats, ethanol caused decreased mean body weights, decreased activity, and impaired maze learning ability. In a chronic dermal toxicity study, no treatment-related effects were noted. Two similar studies with isopropanol caused similar results.

EPA's review of the scientific literature indicates that carcinogenic effects are not expected from the uses of ethanol. In a carcinogenicity study using rats, isopropanol caused an increased incidence of granular kidneys, thickened stomachs, and kidney lesions. A second study using mice also caused increased incidence of stomach and kidney lesions, which were determined not to be of biological significance.

Ethanol is generally recognized as a human developmental neurotoxicant, causing Fetal Alcohol Syndrome in the offspring of mothers who chronically consume high amounts of ethyl alcohol. However, the risk in an industrial environment appears to be minimal.

Developmental toxicity studies using rats and rabbits show that isopropanol causes reduced fetal body weights, decreased maternal body weights, and increases in liver or kidney weights.

Ethanol was negative for mutagenicity effects in six out of seven studies, while isopropanol was negative in all three studies available.

Dietary Exposure

Dietary exposure is not expected to result from the approved uses of ethanol and isopropanol, including the plant regulator (ripener) use.

Occupational and Residential Exposure

Use of aliphatic alcohols may result in high dermal and inhalation exposure of mixers, loaders and applicators, especially when power sprays are used. However, the risk from exposure to these active ingredients is considered to be incidental, considering the frequent intentional human exposures to these substances.

Human Risk Assessment

Aliphatic alcohols are of low acute toxicity. No dietary exposure is expected from their use as pesticides. EPA does not expect developmental or reproductive effects to occur from the potential dermal and inhalation exposures that may result from the registered pesticidal uses of ethanol and isopropanol.

Environmental Assessment

Environmental Fate

Aliphatic alcohols are organic chemical compounds. They are flammable liquids and are highly soluble in water and many organic solvents. Highly volatile liquids, they are stable in water under typical use conditions. EPA does not anticipate significant exposure to the environment from their uses.

Ecological Effects

Ethanol and isopropanol are practically non-toxic to mammals, fish, and aquatic invertebrates.

Ecological Effects Risk Assessment

Aliphatic alcohols are practically non-toxic to all species tested. They are used primarily indoors. Both are highly volatile. Exposure to terrestrial organisms would be extremely minimal.

Additional Data Required

EPA is requiring product-specific data including product chemistry, acute toxicity, and efficacy studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

All aliphatic alcohol end-use products must comply with EPA's current pesticide product labeling requirements. In addition, the following statement must be added to the label of each product, except sterilant products, that is registered for treatment of any medical device or medical equipment surface:

> "This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection."

Regulatory Conclusion

The use of currently registered products containing aliphatic alcohols (ethanol and isopropanol) in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Aliphatic alcohol products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for aliphatic alcohols during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, *GOPHER.EPA.GOV*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the aliphatic alcohols RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the aliphatic alcohols RED, or reregistration of individual products containing aliphatic alcohols, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll- free 1-800-858-7378, between 8:00 am and 8:00 pm Eastern Standard Time, Monday through Friday.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

June 30, 2006

MEMORANDUM

SUBJECT: **Aliphatic Alcohols:** Human Health Chapter of the Reregistration Eligibility Decision (RED) Document. Reregistration Case Number 4004.

DP Barcode: 325712
PC Codes: 079029, 079038, 079059

Regulatory Action: Reregistration Action
Risk Assessment Type: Multiple chemical/no aggregate

FROM: Elissa Reaves, Ph.D., Toxicologist/Risk Assessor
Reregistration Branch 2 (RRB2)
Health Effects Division (7509P)

AND

Shanna Recore, Occupational/Residential Exposure
Yvonne Barnes, Product Chemistry
Reregistration Branch 2 (RRB2)
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Through: William Hazel, Ph.D., Branch Chief
Reregistration Branch 2 (RRB2)
Health Effects Division (7509P)

AND

Alan Nielsen, Senior Scientist
Reregistration Branch 2 (RRB2)
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TO: Tawanda Spears, Chemical Review Manager
Reregistration Branch 3
Special Review and Registration Division (7508P)

1. Executive Summary

This document represents the human health risk assessment chapter of the Reregistration Eligibility Decision (RED) document for the aliphatic alcohols, which include N-decanol, Cx-Cxx alcohols, and fatty alcohols. Aliphatic alcohols are contact sucker control agents used primarily on tobacco. There are no tolerances or tolerance exemptions established for residues of aliphatic alcohols on food.

It should also be noted that the one active product (EPA Reg. No. 53263-29) for the fatty alcohols has recently been voluntarily canceled (Anastasiou Memo, 6/7/06). Therefore, there are no supported products for the active ingredient use of the fatty alcohols. Based on the supported tobacco use, there are no residential uses for the aliphatic alcohols. In addition, the pesticidal uses of the aliphatic alcohols do not involve use on food and, therefore, **are not subject to the Food Quality Protection Act (1996)**.

The available acute toxicity studies indicate the aliphatic alcohols are of low oral and dermal toxicity. Acute inhalation studies with the rat resulted in LD_{50} estimates above the limit concentration of 2 mg/L. Eye irritation studies, however, resulted in severe and sometimes non-reversible eye irritation. Dermal irritation studies revealed slight to moderate irritation in rabbits. The aliphatic alcohols generally did not produce sensitization in tests with guinea pigs.

A 90-day dermal rat study (fatty alcohol blend) resulted in irritation at lower concentrations and before the development of any marginal systemic effects. Slight changes in hematology, clinical chemistry, and organ weights were noted at the limit dose of 1000 mg/kg/day. Severe irritation including fissuring of the skin occurred in 40% of the animals at 100 mg/kg/day and in 80% of the animals at the limit dose. Available developmental toxicity studies (rat) via the inhalation (1-decanol) and oral (fatty alcohol blend) routes of exposure resulted in no adverse effects when examined at the maximum attainable vapor concentration (100 mg/m^3) and oral limit dose (1000 mg/kg/day) based on fetal and maternal parameters. Genotoxicity and mutagenicity studies available were negative and long-term rodent studies to inform the carcinogenic potential of the aliphatic alcohols are not available. However, as a class, the straight chain aliphatic alcohols are generally not carcinogenic. Neurotoxicity information is currently not available, however, there were no clinical signs in any of the acute, subchronic, or developmental toxicity studies to suggest the aliphatic alcohols elicit a neurotoxic effect. Currently there is insufficient hazard concern to warrant a dose-response evaluation or endpoint selection for quantitative risk estimates. Therefore, no acute or chronic endpoints have been identified.

An exposure assessment considers the different pathways (food, water, occupational, and residential) through which exposure to the aliphatic alcohols may occur. Oral exposure through food is not expected since the aliphatic alcohols have no food uses and there are no residential uses. Drinking water is not of concern due to: a) the high vapor pressure and likely volatilization in air; b) atmospheric degradation by reaction with photochemically produced hydroxyl radicals; c) lack of hazard for the oral route of exposure; and d) lack of systemic endpoints based on the available studies. Acute and chronic dietary endpoints have not been selected. Therefore, based on the low hazard concern, lack of food uses, along with no quantitative toxicological endpoints, **a dietary (food and water) risk assessment is not required**.

Since a quantitative dermal endpoint was not identified, no quantitative post application dermal risk was assessed. For uses within the scope of the Worker Protection Standard for Agricultural Pesticides (40 CFR 170), a restricted entry interval (REI) must be established. The REI should be based on the category assigned to the acute dermal toxicity, skin irritation potential, and eye irritation potential of the active ingredient. The appropriate REI is 48 hours if any of the three categories are classified as toxicity category one.

For occupational handler exposure of aliphatic alcohols-containing products, dermal, eye and respiratory irritation effects are addressed through precautionary labeling requirements for use of Personal Protective Equipment (PPE). Most of the current labels for N-decanol, alcohols (Cx-Cxx), and fatty alcohols require long pants, chemical resistant gloves, shoes plus socks, and protective eyewear.

Based on the lack of food and residential uses and low hazard via the oral, dermal, and inhalation routes of exposure, **quantitative dietary (food and water) and occupational/residential exposure assessments have not been conducted.** Additionally, the aliphatic alcohols are 'non-food use' chemicals and are not subject to the amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA) promulgated under the Food Quality Protection Act (FQPA) of 1996, and **an aggregate risk assessment is not required.**

2. Introduction

a. Scope of Risk Assessment

This risk assessment evaluates the aliphatic alcohols that are comprised of decanol, alcohols Cx-Cxx, and fatty alcohols. Because of the low hazard concern of the aliphatic alcohols, no toxicological endpoints have been selected for dietary or exposure risk assessment purposes.

b. Ingredient Profile

The review of the product chemistry for the aliphatic alcohols was not based on a single chemical or pc code but rather based on the collective nature of the aliphatic alcohols.

i. Structure and Nomenclature

Table 1 Nomenclature for Aliphatic Alcohols		
Chemical structure	 n-Decyl Alcohol	
Common name	Simple Aliphatic Alcohol: Ethanol	1-Decanol
Molecular formula	C2HsOH	CH3(CH2)9-OH
Molecular weight	46.068 g/mol	158.29 g/mol
IUPAC name (denotation)	lnChl=1/C2H6O/c1-2-3/h3H,2H2,1H3	Not Reported
CAS name	Ethyl Alcohol	n-Decyl Alcohol
CAS number	64-17-5	112-30-1
PC Code	001501	079038

ii. Physical and Chemical Properties

Table 2. Physicochemical Properties Aliphatic Alcohols		
Parameter	Simple Aliphatic Alcohol Value/Reference	Aliphatic Alcohol: 1-Deconol Value/Reference
Melting point/range	-114.1 to-117 degrees Celsius Merck 12th Edition; MSDS	6.9 deorees Celsius **MSDS**
Vapor Density at 20 degrees Celsius	1.59 ChemFinder	**4.5** **MSDS**
Water solubility	Fully miscible; >=10 g/100 ml at 23 °C Riddick, J.A. et al. (1996); ChemFinder	37 mg/L ; Insoluble; poor Barton, AFM (1984)
Solvent solubility at: 20 degrees Celsius	Organic solids of low molecular weight are usually soluble in ethanol. - Among ionic **compounds,** many mono-valent salts are at least somewhat soluble in ethanol, with salts of large, **polarizable** ions being more soluble than salts of smaller ions. - Most salts of polyvalent ions are practically insoluble in ethanol. 1) Vaija, et al., *Appl. Biochem. Biotechno/.,1,*51,1982. 2) J.M. Lee and J. Woodward, *Biotech. Bioeng.,* 25, 2441, 1983. 3) Encyclopedia	Not reported
Vapor pressure	40 mmHg at 19°C 44 mmHg at 20°c 59.3 mmHg at 25°C Daubert, TE & Danner, RP (1985;) **MSDS**	0.00851 mmHg at 25°C Daubert, TE & Danner, RP (1989)
	15.9 (H+ from OH group)	Not reported

Table 2. Physicochemical Properties Aliphatic Alcohols

Parameter	Simple Aliphatic Alcohol Value/Reference	Aliphatic Alcohol : 1-Deconol Value/Reference
Dissociation constan,t pK.,	Hansch, c et al. (1995)	
Octanol/water partition coefficient	Log Kaw Log P = -0.14 Hansch, c et al. (1995)	Log Kaw Log P = 3.79
		Hansch, c et al. (1995)
UV/visible absorption spectrum	Data Gap	Data Gap

Refer to http://www.epa.gov/athens/research/regsupport/properties .html for further details relating to physical and chemical chemistry

i. Summary of Pesticidal Uses

All three chemicals that comprise the reregistration case for the aliphatic alcohols serve as plant regulators . N-Decanol, alcohols (Cx-Cxx), and fatty alcohols are formulated as liquids and are applied via the following methods: groundboom sprayer, backpack sprayer, handgun sprayer, high pressure handwands and low pressure handwands.

ii. Tolerances

• Established Tolerances & Tolerance Exemptions

As the aliphatic alcohols are not registered for use on food crops, there are no tolerances established for residues on food. Similarly, there are currently no tolerance exemptions for the aliphatic alcohols.

3. Hazard Characterization and Assessment

The available toxicity database for the aliphatic alcohols consists of acute toxicity, irritation, and sensitization studies. In addition, there are developmental rat (oral and inhalation) toxicity studies and a 90-day rat (dermal) study. Mutagenicity studies available include the Ames, micronucleus, and gene mutation assays. Sources from the published literature are also included in this hazard assessment. The combination of the published literature and submitted toxicity studies are sufficient to assess the pesticidal nonfood uses of the aliphatic alcohols. Based on the low hazard concern via the oral, dermal, and inhalation routes of exposure, a qualitative hazard assessment is appropriate for the aliphatic alcohols.

1-Decanol has been found as a natural component in apples and oranges and has been reported in essential oils of ambrette seeds, almond flowers, citrus oils and fermented beverages (as cited in HSDB, 2005). 1-Decanol is also a permitted food additive for direct addition to food for human consumption as a synthetic flavoring substance and adjuvant in accordance with the following FDA conditions: I) the quantity added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritive, or other technical effect in food, and 2) when intended for use in or on food it is of appropriate food grade and is prepared and handled as a food ingredient (21 CFR

172.515). There is currently no known mode of action for the aliphatic alcohols. There are currently no guideline metabolism studies in rats available for the aliphatic alcohols.

The acute toxicity studies available for all three of the aliphatic alcohols (PC Codes 079038, 079029, 079059) are listed in Table A1. The available acute toxicity studies indicate the aliphatic alcohols are of low oral and dermal toxicity (Toxicity Categories III and IV). Acute inhalation studies with the rat resulted in LD_{50} estimates above the limit concentration of 2 mg/L. However, eye irritation studies resulted in severe and sometimes non-reversible eye irritation (Toxicity Category I, II, and III). Dermal irritation studies revealed slight to moderate irritation in rabbits (Toxicity Category III and IV). The aliphatic alcohols generally did not produce sensitization in tests with guinea pigs.

Oral subchronic toxicity studies are not available for the aliphatic alcohols. However, a 90-day dermal toxicity study in the rat is available (MRID 43701201). Results of the dermal exposure to a fatty alcohol blend (56.7% decanol, 42.7% octanol) at 0, 100, 300, or 1000 mg/kg for 5 days/week for 13 weeks included erythema, edema, desquamation, eschar formation and exfoliation of all treated animals. The irritation occurred early (within two weeks of the application process) with irritation apparent in a dose-response fashion. Fissuring of the skin occurred in 40% of animals at 100 mg/kg/day while in 80% of animals at the limit dose of 1000 mg/kg/day. Decreased body weight was also observed at the limit dose (-19% M, -13% F). Slight changes in hematological parameters, clinical chemistry, and organ weight changes were apparent at the limit dose. No other gross or histopathological organ pathology was associated with the skin application of the fatty alcohol blend. The dermal irritation NOAEL was not established with an irritation LOAEL of 100 mg/kg based on severe irritation. The systemic NOAEL was 300 mg/kg/day with systemic LOAEL of 1000 mg/kg/day, based on hematological, clinical chemistry, and organ weight changes.

Developmental toxicity studies via the inhalation (1-decanol) and oral (fatty alcohol blend) routes of exposure resulted in no adverse effects based on fetal and maternal parameters. A developmental inhalation study exposed Sprague-Dawley rats (15) to 15 ppm (100 mg/m^3) 1-decanol for 7 hours per day on GD 1-19 (Nelson *et al.*, 1990a; Nelson *et al.*, 1990b). The concentration of 1-decanol selected was based on the highest concentration that could be generated as a vapor at an average daily chamber temperature of 70-80°F. No treatment-related effects were observed in pregnant females or fetuses including frequency of resorptions, fetal weights, or skeletal/visceral malformations. An oral developmental study exposed 25 female Sprague-Dawley rats/dose at 0, 125, 375, or 1000 mg/kg/day to a fatty alcohol blend (55% decanol; 40.7% octanol) on GD 6-16 (MRID 42609301). The maternal NOAEL was 375 mg/kg/day and LOAEL was 1000 mg/kg/day (limit dose), based on increased incidence of salivation (67%). No adverse effects were observed in the offspring. The developmental NOAEL was 1000 mg/kg/day (HDT) with no LOAEL being established.

Genotoxicity and mutagenicity studies available were negative for reverse gene mutations in *Salmonella typhimurium*, not mutagenic in 2 independent assays with/without activation at levels ranging from 9.4 μg/ml to 37.5 μg/ml, and negative for micronucleus induction in bone marrow cells of male and female CD-1 mice harvested 24 or 48 hrs post-administration of 3 daily doses of 500, 1000, or 2000 mg/kg/day. There is currently no long-term rodent information regarding the carcinogenic potential for the aliphatic alcohols.

Neurotoxicity information is currently not available. However, there were no clinical signs in any of the acute, subchronic, or developmental toxicity studies to suggest the aliphatic alcohols elicit a neurotoxic effect.

4. Endpoint Selection

Based on the available data, there is no evidence to suggest that the aliphatic alcohols cause increased susceptibility in infants and children. Furthermore, based on the low hazard concern from the available studies, **no endpoints of toxicological concern have been identified for risk assessment purposes.**

5. Incident Report

Although a summary of the incident data for the aliphatic alcohols is currently not available for inclusion in this assessment, it should be noted that the aliphatic alcohols are scheduled to be reviewed. The Agency will consider the results of the incident review once the evaluation is available.

6. Exposure Assessment

a. Dietary Exposure (food and drinking water)

An exposure assessment considers the different pathways (food, water, occupational, and residential) through which exposure to the aliphatic alcohols may occur. Drinking water is not of concern due to: a) the high vapor pressure and likely volatilization in air; b) atmospheric degradation by reaction with photochemically produced hydroxyl radicals (HSDB, 2005); c) lack of hazard for the oral route of exposure; and d) lack of systemic endpoints based on the available studies. Acute and chronic dietary endpoints have not been selected. Therefore, based on the lack of food uses and the low hazard concern of the aliphatic alcohols along with no acute or chronic dietary endpoints being identified, **a dietary (food and water) risk assessment is not appropriate**.

b. Occupational and Residential Exposure

Aliphatic alcohols are contact sucker control agents used primarily on tobacco [N-decanol, alcohols (Cx-Cxx), fatty alcohols]. Currently there are no residential uses for the aliphatic alcohols. There is potential for exposure of occupational mixers, loaders, applicators, and post-application workers to aliphatic alcohol formulations. However, due to the low hazard concern of the aliphatic alcohols, no dermal, oral, or inhalation endpoints of toxicological concern have been identified for the aliphatic alcohols. Therefore, an **occupational/residential exposure assessment is not required.**

N-Decanol, alcohols (Cx-Cxx), and fatty alcohols are formulated as liquids and are applied via the following methods: groundboom sprayer, backpack sprayer, handgun sprayer, high pressure handwands and low pressure handwands.

Available dermal studies indicate that aliphatic alcohols are acutely irritating with any possible stress related changes systemically occurring at higher concentrations and over repeated dermal exposure. Mammals are, therefore, more sensitive to irritation than to any systemic effects and so dermal exposure should be avoided. Available inhalation toxicity studies indicate that aliphatic alcohols are of low toxicity via the inhalation route.

Due to the low hazard profile and lack of endpoint selection for the dermal route of exposure, no postapplication dermal risk was assessed. For uses within the scope of the Worker Protection Standard for Agricultural Pesticides (40 CFR 170), a restricted entry interval (REI) must be established. The REI should be based on the category assigned to the acute dermal toxicity, skin irritation potential, and eye irritation potential of the active ingredient. The appropriate REI is 48 hours if any of the three categories are classified as toxicity category one.

For occupational uses of aliphatic alcohol-containing products, dermal, eye and respiratory irritation effects are addressed through precautionary labeling requirements for use of Personal Protective Equipment (PPE). Most of the current labels for N- decanol, alcohols (Cx-Cxx), and fatty alcohols require long pants, chemical resistant gloves, shoes plus socks, and protective eyewear.

Table 3. Summary of Maximum Application Rates for Relrlstered Aliphatic Alcohol Products

Chemical	Crop	Target	Formulation	Maximum Application Rate	Max#of applications	Application Equipment
N-Decanol	Tobacco	foliar	EC	21.5 lbs ai/acre for hand sprayer 18.9 lbs ai/acre for groundboom	2	groundboom sprayer, backpack sprayer, handgun sprayer, high pressure handwands and low pressure handwands
Alcohols (Cx-Cxx)	Tobacco	foliar	Liquid (EC,SC)	21.7 lbs ai/acre	3	
Fatty Alcohols	Tobacco	foliar	EC	14.19 lbs ai/acre	2	

7. Cumulative Exposure

As the aliphatic alcohols are not registered for use on food crops, the requirements of FQPA are not applicable and a cumulative risk assessment is not appropriate.

8. Summary

1-Decanol has been found as a natural component in apples and oranges and has been reported in essential oils of ambrette seeds, almond flowers, citrus oils and fermented beverages. 1-Decanol is also a permitted food additive for direct addition to food for human consumption as a synthetic flavoring substance and adjuvant in accordance with the FDA. Aliphatic alcohols are contact sucker control agents used primarily on tobacco [N-decanol, alcohols (Cx-Cxx), fatty alcohols]. Currently there are no residential uses for the aliphatic alcohols.

There is potential for exposure of occupational mixers, loaders, and applicators to aliphatic alcohol formulations. However, endpoint selection was not warranted based on the available toxicity data. Therefore, occupational handler risk assessments cannot be conducted and are not appropriate for the aliphatic alcohols.

Based on the hazard profile for dermal exposure to aliphatic alcohols, no post-application dermal risk was assessed. For uses within the scope of the Worker Protection Standard for Agricultural Pesticides (40 CFR 170), a restricted entry interval (REI) must be established. The REI should be based on the category assigned to the acute dermal toxicity, skin irritation potential, and eye irritation potential of the active ingredient. The appropriate REI is 48 hours if any of the three categories are classified as toxicity category one.

For occupational uses of aliphatic alcohol-containing products, dermal, eye and respiratory irritation effects are addressed through precautionary labeling requirements for use of PPE. Most of the current labels for N-decanol, alcohols (Cx-Cxx), and fatty alcohols require long pants, chemical resistant gloves, shoes plus socks, and protective eyewear.

Due to the toxicity profile of the aliphatic alcohols, toxicological endpoints of concern were not warranted for risk assessment purposes. **Quantitative dietary (food and water) and occupational/residential exposure assessments, therefore, have not been conducted.** Additionally, as the aliphatic alcohols are 'nonfood use' chemicals and are not subject to FQPA, **an aggregate risk assessment is not required.**

Appendix 1: Toxicological Profile Tables for the Aliphatic Alcohols

Table Al: Acute Toxicity Data for the Aliphatic Alcohols

Guideline No.	Study Type	PC Code	MRID	Results	Toxicity Category
870.1100 81-l	Acute oral [rat]	079029 Fatty Alcohols	00142279	85% fatty alcohols, LD50 = 29.3 mg/ml (95% CI of 26.5 to 32.5) (approximately 25 g/kg)	IV

Table Al: Acute Toxicity Data for the Aliphatic Alcohols

870.1100 81-1	Acute oral [rat)	079038 1-Decanol	44460401	79.2% decanol No deaths at 2000 mg/kg LD50>2000mg/kg	III
870.11 00 81-1	Acute oral [rat]	079038 1-Decanol	46004601	79% decanol No deaths at 2000 mg/kg LD50>2000 mg/kg	Ill
870.1100 81-1	Acute oral [rat]	079038 1-Decanol	45507901	37.98% decanol No deaths LD50>3000 mg/kg	III
870.1100 81-1	Acute oral [rat]	079038 1-Decanol	0060309 0064859	78.4% decanol , LD50 = 5000 mg/kg	IV
870.1200 81-2	Acute dermal [rat]	079038 1-Decanol	44460402	79.2% decanol No systemic clinical signs, no deaths, very slight erythema at 2000 and 4000 mg/kg LD50>4000 mg/kg	III
870.1200 81-2	Acute dermal (rat)	079038 1-Decanol	46004602	79% decanol No deaths , no systemic clinical signs, LD50> 2000 mg/kg	III
870.1200 81-2	Acute dermal (rat]	079038 1-Decanol	45507902	37.98% decanol No deaths, no clinical signs LD50>4000 mg/kg	III
870.1200 81-2	Acute dermal [rabbit]	079038 1-Decanol	0046993 0046994	78.4% decanol , LD50 = 5000 mg/kg	IV
870.1300 81-3	Acute inhalation (rat)	079038 1-Decanol	44460403	79.2% decanol (4 hr nose only) 1 male died Day 2 post-exposure, survivors recovered from 7 to 10 post-exposure LC50>5.07 mg/L.	IV
870.1300 81-3	Acute inhalation [rat]	079038 1-Decanol	46004603	79% decanol No deaths . LC50>3.35 mg/L	IV
870.1300 81-3	Acute inhalation [rat]	079038 1-Decanol	45517901	37.98% decanol (4 hr nose only) No deaths LC50>7.08 mg/L	IV
870.2400 81-4	Acute eye irritation [rabbit)	079038 1-Decanol	44460404 44578801	79.2% decanol Corneal opacity in all treated eye at 7 days. Conjunctive irritation until 7 and 14 days. Irreversible vascularisation in one eye until Day 21.	I

Table Al: Acute Toxicity Data for the Aliphatic Alcohols

870.2400 81-4	Acute eye irritation [rabbit]	079038 1-Decanol	46004604	79% decanol Corneal opacity, irritation cleared by 6 days. Conjunctive irritation, redness, chemosis cleared by 6 days. Moderately irritating.	III
870.2400 81-4	Acute eye irritation [rabbit)	079038 1-Decanol	45517902	37.98% decanol Corneal involvement or irritation clearing in 7 days or less	Ill
870.2400 81-4	Acute eye irritation [rabbit)	079029 Fatty Alcohols	44340701	100% fatty alcohols, *All* 6 rabbits showed moderate to severe irritation . Opacity up to 7 days. Slight iritis with conjunctiva! redness to Day 6, slight chemosis to Day 7 and slight to severe discharge to Day 8.	II-III
870.2400 81-4	Acute eye irritation [rabbit)	079038 1-Decanol	--	78.4% decanol, irreversible corneal opacity in all 6 animals . Severe eye irritation.	I
870.2500 . 81-5	Acute dermal irritation [rabbit]	079038 1-Decanol	44407601 44460405	79.2% decanol Primary irritation index 4.0. Moderate irritation.	III
870.2500. 81-5	Acute dermal irritation [rabbit]	079038 1-Decanol	46004605	79% decanol Primary irritation index 0.0	IV
870.2500 . 81-5	Acute dermal irritation [rabbit]	079038 1-Decanol	45517903	37.98% decanol Primary irritation index 0.0. Non-irritant.	JV
870.2500 . 81-5	Acute dermal irritation [rabbit)	079038 1-Decanol	--	PIS 2.04. Erythema, eschar formation and edema evident at 72 hrs. Mild irritant.	III
870.2600 81-6	Skin sensitization [guinea pig]	079029 Fatty Alcohols	43386201	Fatty alcohol blend C6-C12 (99%) All animals survived. No adverse effect on body weight. Not a dermal sensitizer	NA
870.2600 81-6	Skin sensitization [guinea pig]	079038 1-Decanol	44407602 44460406	79.2% decanol No change in body weight. 55% (I 1/20) sensitization rate.	NA

Table Al: Acute Toxicity Data for the Aliphatic Alcohols

870.2600 81-6	Skin sensitization [guinea pig]	079038 1-Decanol	46004606	79% decanol Not a dermal sensitizer	NA
870.2600 81-6	Skin sensitization [guinea pig]	079038 1-Decanol	45507903	37.98% decanol Not a dermal sensitizer	NA

Table A2: Subchronic, Chronic, Developmental, Reproductive and Other Toxicity Profile on the Fatty Alcohols

Guideline#/ Study Type	**MRID# (year)/ Classification /Doses**	**Results**
870.3250 82-3 90-Day dermal toxicity	43701201 (J 995) Acceptable/Guideline IO Sprague-Dawley rats /sex/dose of 0, I 00, 300, or 1000 mg/kg for 5 days/week for 13 weeks	Fatty alcohol blend (56.7% decanol, 42.7% octanol) Primary adverse clinical signs included erythema , edema, desquamation, eschar formation and exfoliation of all treated animals. Irritation apparent within 2 weeks after dermal application. Fissuring of skin observed in 40% of animals in low dose while 80% of animals in high dose. High doses animals exhibited vocalization and hypersensitivity to touch . Body weight was reduced in high dose (-19% M, -13% F) animals . Marginally increased adrenal glands in high-dose animals, slightly reduced RBC counts, hematocrit, and increased WBC and platelet counts in high-dose animals . No gross or histological alterations other than severe irritation. **Dermal irritation NOAEL not established,** LOAEL 100 mg/kg based on severe irritation. **Systemic NOAEL 300 mg/kg/day,** LOAEL 1000 mg/kg/day (LTD), based on slight changes in hematological and clinical chemistry parameters, and decreased bodyweight.
Developmental Range Finding	42634201 (1991) Rats	Fatty Alcohol Blend: 96.6%. Dose levels tested: 125, 375, 750, and 1000 mg /kg/day. No treatment-related effects were seen in the dams or in the fetuses of dams given the highest dose. Based on this study, does level selected for the main study were: 0, 125, 375 or 1000 mg/kg/day.
870.3700a 83-3a Developmental Toxicity (rat)	4260930 I (1992) Acceptable/Guideline 25 F Sprague-Dawley /dose at 0, 125 , 375, 1000 mg/kg/day on GD 6-16	Fatty alcohol blend (55% decanol ; 40.7% octanol) Maternal NOAEL 375 mg/kg/day Maternal LOAEL 1000 mg/kg/day, based on increased incidence of salivation (67%). Developmental NOAEL 1000 mg/kg/day Developmental LOAEL not established

Table Al: Subcbronic, Chronic, Developmental, Reproductive and Other Toxicity Proftle on the Fatty Alcohols		
Guideline#/ Study Type	**MRID# (year)/ Classification /Doses**	**Results**
Developmental Toxici ty (rat)	Nelson et al., 1990a, 1990b 100 mg/m^3 (max vapor achievable) 15 F Sprague-Dawley/ 7 hrs/day on GD 1-19	Dams weighed daily for first week and weekly thereafter. Rats sacrificed on GD 20. No treatment related effects observed in pregnant females , frequency of resorptions, fetal weights, or skeletal /visceral malformations.
Gene Mutation 84-2 870.5100 *(Salmonella typhimurium)*	42372002 (1992) Acceptable /Guideline (55.3% decanol, 40.7% octanol)	Negative for reverse gene mutations in *Salmonella typhimurium* TA 1535 , TA 1537, TA 1538 , TA98, and TA I 00 in presence or absence of S9 activation to 6 doses from 1.5 µg/plate to 500 µg/plate (2 independent trials) . Cytotoxicity was apparent for all strains at 500 µg/plate +/- S9.
Gene Mutation 870.5300 84-2 (mouse lymphoma cells)	42372003 (1992) Acceptable/Guideline (55.3% decanol, 40.7% octanol)	Not mutagenic in 2 independent assays with/without activation. Initial assay non-activated & S9 levels ranged from 9.4 µg/ml to 37.5 µg/ml; doses of75 µg/ml severely cytotoxic . Confirmatory assay with 10-50 µg/ml - S9 and 30-70 µg/ml +S9 were evaluated with severe cytotoxicity observed at non-activated levels (60 µg/ml and at S9 activation 80 µg/ml).
Micronucleus 870.5395 84-2 (mouse)	42372001 (1992) Acceptable/Guideline (55.3% decanol, 40.7% octanol)	Negative for micronucleus induction in bone marrow cells of Male and Female CD-I mice harvested 24 or 48 hrs post-administration of 3 daily doses of 500, I 000, or 2000 mg/kg/day. o overt toxicity in any treated animal or target organ in any treatment group.

References:

Nelson BK, Brightwell WS, and Krieg EF Jr (1990a). Developmental toxicology of industrial alcohols: A summary of 13 alcohols administered by inhalation to rats.
Toxicology and Industrial Health. Vol 6 (3/4): 373-387.

Nelson BK, Brightwell WS, Khan A, Krieg EF Jr, and Haberman AM (1990b). Developmental toxicology assessment of 1-octanol, 1-nonanol, and 1-decanol administered by inhalation to rats. Journal of the American College of Toxicology. Vol 9(1): 93-97.

HSDB, 2005. Hazardous Substances Data Bank. National Library of Medicine. Search Term: 1-Decanol. http://toxnet.nlm.nih.gov/cg i-bin/sis/search/f?./temp/~fK9cOq:1

ITEM B.13 Petition Justification Statement

Inclusion of a Synthetic Substance allowed for use in Organic Tobacco Crop Production
on The National List Reference 205.601 (k) Synthetic Growth Regulator
and National List Section 205.601 (k)(2) Active IngredientC_6, C_8, C_{10}, C_{12} - ***Naturally Derived Fatty Alcohol***
Annotation. For Use on Organic Tobacco Crops as a Plant Contact Agent

I. Explain why the synthetic substance is necessary for the production of an organic product?

Sucker Control / Efficacy on Tobacco:

The Fatty Alcohols being petitioned for use in organic crop production, have been used on farms for several decades with a positive and effective use history, has an excellent record in the field, the environment, and human safety; with cultural benefits.

According to the North Carolina Department of Agriculture, “controlling suckers in tobacco is a critical component of any production system. Both yield and quality are reduced by inadequate sucker control. The fatty alcohols are efficacious sucker control materials and greatly reduce the labor required in tobacco production and overall acreage” and are essential for organic tobacco production and supports the continuous rotation of crops such as sweet potatoes, small grains and other crops; therefore, increasing the health of the soil and the biodiversity of the farm system.

- The report by Dr. Loren Fisher, Department of Crop and soil Sciences, North Carolina State University, that is included outlines the “Importance of Effective Sucker Control in Organic Tobacco production.
- Historical By: Roland Cargill
- Fatty Alcohol vs Mineral Oil By: Roland Cargill
- 2018 North Carolina State University Sucker Control Tests
- Right Time First Spray 10% Chemical Topping by: Dr. William Collins

Importance of Effective Sucker Control to Organic Tobacco Production

Loren R. Fisher
Department of Crop and Soil Sciences
North Carolina State University

Suckers in tobacco are shoots that develop in the leaf axils after removal of the flower. If sucker growth is not controlled, shoots will produce additional flowering structures and become a sink for energy in the plant. Flower removal and control of sucker growth is essential in tobacco production to maximize leaf yield and quality. Without sucker control after flower removal, yield is reduced 35-40% and leaf quality is substantially reduced. EPA registration of sucker control chemicals in conventional production systems is widely considered one of the most important developments that allowed growers to reduce labor inputs from 600 man hours/Acre down to approximately 60 man hours/Acre in the last 50 years.

Prior to the registration of O-Tac for sucker growth suppression in organic tobacco, growers did not have any viable and effective options for acceptable chemical control of sucker growth compared to conventional growers. Growers had to employ ineffective chemical control measures, such as mineral oil, and then remove suckers by hand, which resulted in a high labor requirement and reduced yield. In many cases, growers reported applying mineral oil (or related products) by “hand” with backpack because alternatives to fatty alcohols were not effective when applied with mechanical sprayers. This method was extremely laborious and tedious and created undue exposure of labor to extreme working conditions. It is estimated that an additional 30 hours of labor per acre are required to manage suckers without using a fatty alcohol, or an additional labor cost of $338 per acre. It is also estimated that there is an additional 5-8% ($375-$600 per acre) loss in tobacco value from reduced yield and quality due to poor sucker control. Growers report that the lack of effective sucker control products registered for use in organic tobacco production, and the subsequent labor requirement for sucker management, were the most limiting factor to either entering the market or expanding organic production. In addition, the tobacco industry has reported negative effects of mineral oil on marketable consumer products, specifically staining of cigarette paper.

It is estimated that O-Tac is used on approximately 20,000 acres (estimated 500+ farm families) across the tobacco producing states in the US. Approximately 1/3 of the farms where O-Tac is used are producing certified organic tobacco with the remainder producing pesticide residue free tobacco. Acreage of organic tobacco has increased dramatically since the registration of O-Tac as growers employed this effective sucker control measure which reduced management costs and allowed for expansion of organic tobacco production without substantially increasing labor inputs.

The total value of organic tobacco production in the United States was estimated at $49.5 million and included production in North Carolina, Virginia, Kentucky, Tennessee, Pennsylvania, and

Wisconsin. In North Carolina, tobacco leads the state in total value of organic production totaling over $29 million in 2015 (estimated at less than $3.5 million in 2011) with the next highest crop, sweet potato, at just over $10 million (USDA Certified Organic Production Report, 2016). In 2016, Gary Bullen, with the NCSU Department of Agriculture and Resource Economics surveyed 25 organic tobacco growers in NC, representing approximately 1,250 acres of organic tobacco (or 30% of the total acreage in NC in 2016) , to develop an estimated production budget. The budget is attached along with a conventional budget for comparison. As you will note from the budget, organic tobacco production can be profitable (quadruple the profit of conventional tobacco on average) and is very important to the economic viability of farm families in tobacco producing areas of the United States. This is especially true for smaller farms (common in tobacco producing areas and with organic producers in general) with limited total farm acreage where profit per acre of farmland managed must be maximized to sustain the operation. Because of the potential profitability of organic tobacco in an organic cropping system rotation, growers are now producing other organic crops such as peanut, soybean, small grain, sweet potatoes, and corn that otherwise would not have been produced. For every acre of organic tobacco in production, two additional acres of organic crops are also brought into production as farmers employ a three year crop rotation. In North Carolina alone, it is estimated that organic tobacco acreage has increased by approximately 2,500 acres since 2011, resulting in an additional 5,000 acres of additional crops brought into organic production.

Renee Allen

From:	Loren Fisher <lrfishe1@ncsu.edu>
Sent:	Friday, January 27, 2017 4:43 PM
To:	Renee Allen
Subject:	Fwd: DRAFT Organic tobacco budget
Attachments:	Untitled attachment 02504.htm; Organic Tobhand-2017.pdf

Begin forwarded message:

> **From:** Stephen Bullen <sgbullen@ncsu.edu>
> **Date:** January 27, 2017 at 11:07:55 AM EST
> **To:** Loren Fisher <Loren_Fisher@ncsu.edu>
> **Subject: DRAFT Organic tobacco budget**
>
> Loren,
>
> Please find attached the draft organic tobacco budget. This budget was developed from individual and group farmers interviews in summer and fall of 2016. I meet with over 20 farmers during these meeting. Many of the farmers total me their cost for organic tobacco production was between $5,000 and $5,500. Several of the farmers I interviewed were first or second year organic growers. I do not believe they have totally established their organic production practices. The areas that concerned the new farmers were weed control, aphids and organic certification paper work. I have not added to cost of organic certification to the budget yet. There are some additional administrative time for organic production records. Farmers estimated the time was 1-2 hour per week for the production season. I think the labor hours are higher than the 161 hours we have now. I plan to meet with organic tobacco farmers to verify the labor hours we have in budget.
>
> Farmer were satisfied with their sucker control programs. Most were topping and sucking around 4 times. Organic tobacco production would be much more difficult without O-Tac. Many did have concern about aphids control. In the Piedmont region most organic tobacco did not have another crop that would work in the required three year crop rotation, so most were growing wheat or some grass or fallow the second and third year. The tobacco returns are being spread over three years. The farmers in East did have more organic crop options. Organic tobacco should be considered based on the whole rotation not just the one year.
>
> Gary
>
> --
>
> S. Gary Bullen
>
> NC State University

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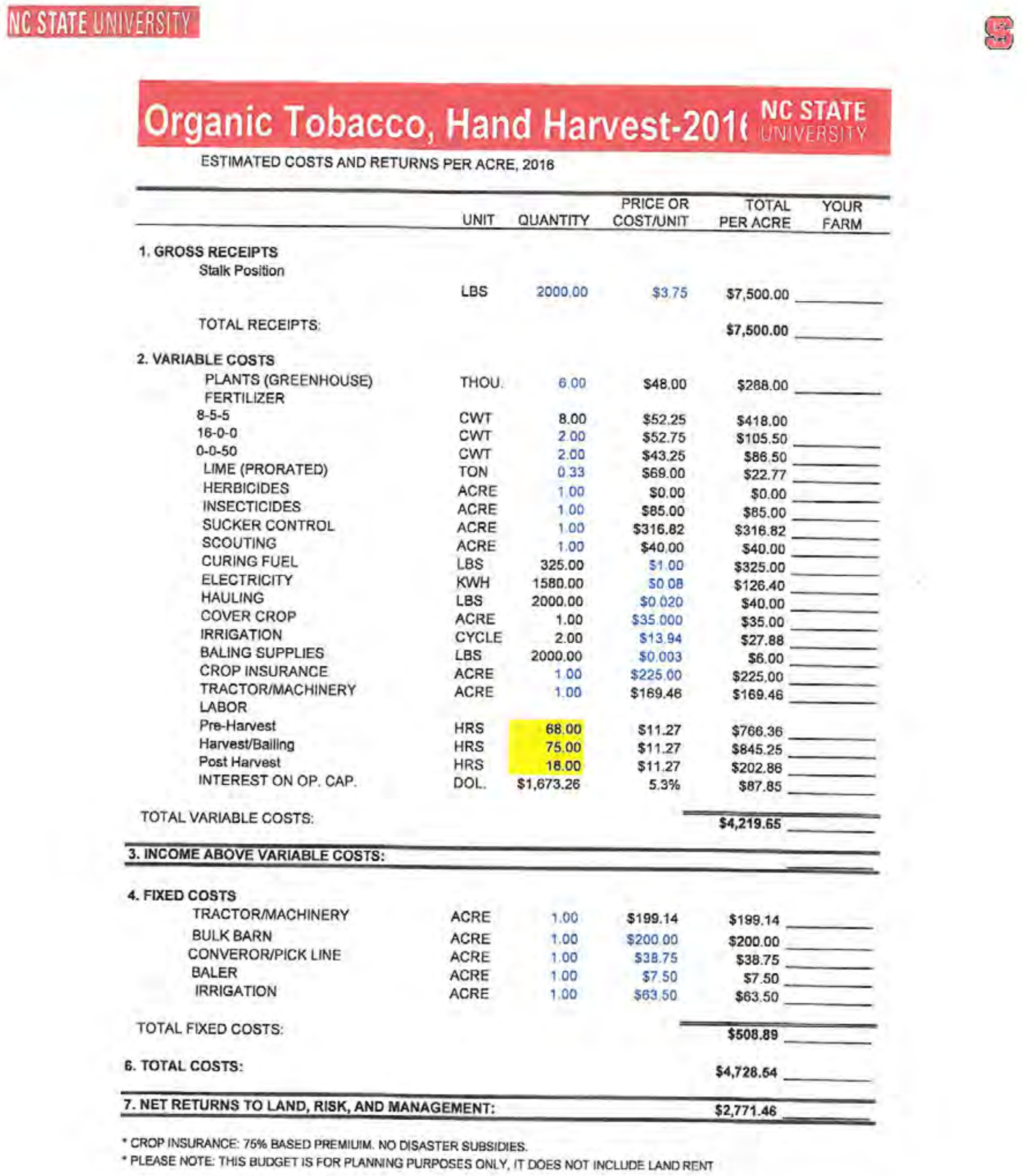
3326 Nelson Hall
Campus Box 8109
Raleigh, NC 27695-8109

Ph: 919.515.6096
Fax: 919.515.6268



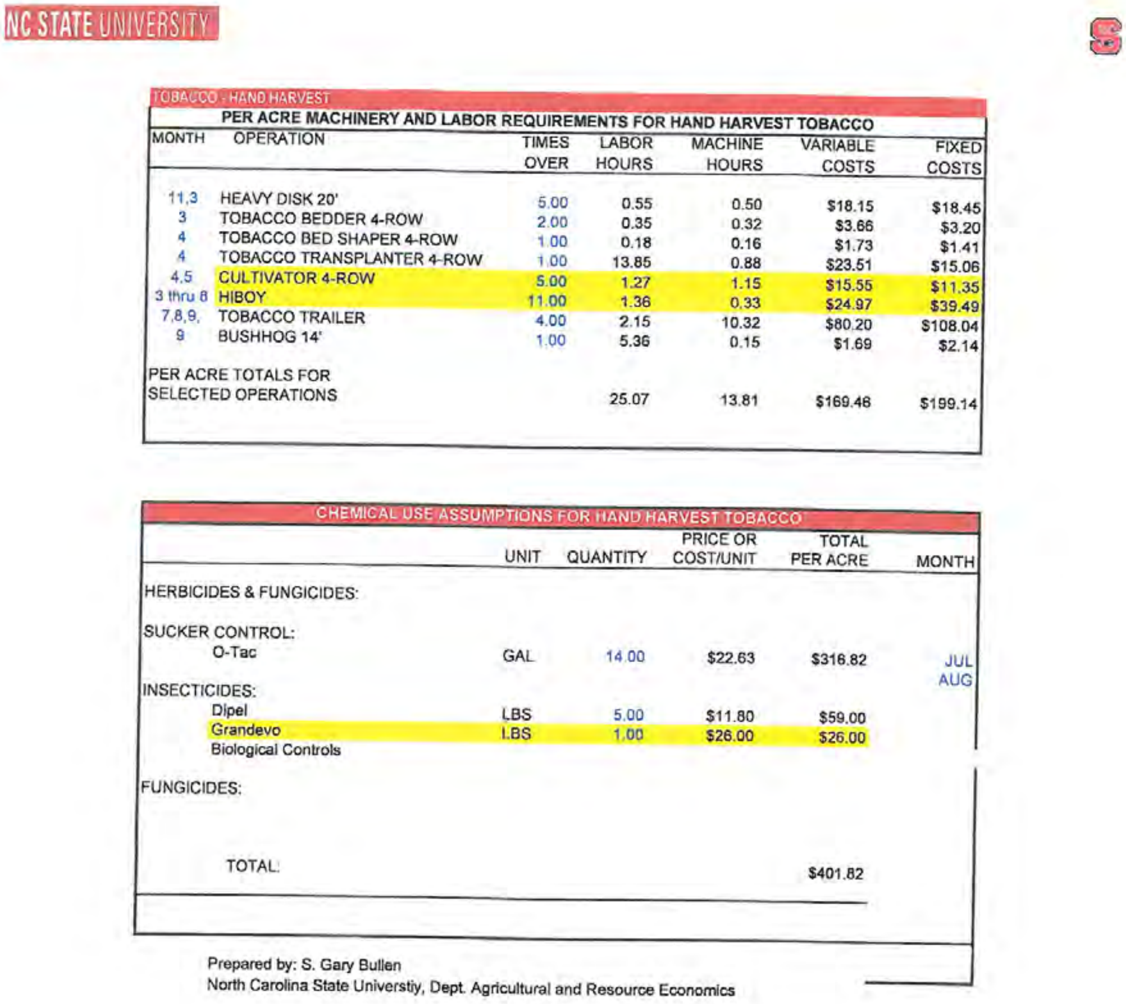
Organic Tobacco, Hand Harvest-201

ESTIMATED COSTS AND RETURNS PER ACRE, 2016

	UNIT	QUANTITY	PRICE OR COST/UNIT	TOTAL PER ACRE	YOUR FARM
1. GROSS RECEIPTS					
Stalk Position					
	LBS	2000.00	$3.75	$7,500.00	
TOTAL RECEIPTS:				**$7,500.00**	
2. VARIABLE COSTS					
PLANTS (GREENHOUSE)	THOU.	6.00	$48.00	$288.00	
FERTILIZER					
8-5-5	CWT	8.00	$52.25	$418.00	
16-0-0	CWT	2.00	$52.75	$105.50	
0-0-50	CWT	2.00	$43.25	$86.50	
LIME (PRORATED)	TON	0.33	$69.00	$22.77	
HERBICIDES	ACRE	1.00	$0.00	$0.00	
INSECTICIDES	ACRE	1.00	$85.00	$85.00	
SUCKER CONTROL	ACRE	1.00	$316.82	$316.82	
SCOUTING	ACRE	1.00	$40.00	$40.00	
CURING FUEL	LBS	325.00	$1.00	$325.00	
ELECTRICITY	KWH	1580.00	$0.08	$126.40	
HAULING	LBS	2000.00	$0.020	$40.00	
COVER CROP	ACRE	1.00	$35.000	$35.00	
IRRIGATION	CYCLE	2.00	$13.94	$27.88	
BALING SUPPLIES	LBS	2000.00	$0.003	$6.00	
CROP INSURANCE	ACRE	1.00	$225.00	$225.00	
TRACTOR/MACHINERY	ACRE	1.00	$169.46	$169.46	
LABOR					
Pre-Harvest	HRS	68.00	$11.27	$766.36	
Harvest/Bailing	HRS	75.00	$11.27	$845.25	
Post Harvest	HRS	18.00	$11.27	$202.86	
INTEREST ON OP. CAP.	DOL.	$1,673.26	5.3%	$87.85	
TOTAL VARIABLE COSTS:				**$4,219.65**	
3. INCOME ABOVE VARIABLE COSTS:					
4. FIXED COSTS					
TRACTOR/MACHINERY	ACRE	1.00	$199.14	$199.14	
BULK BARN	ACRE	1.00	$200.00	$200.00	
CONVEROR/PICK LINE	ACRE	1.00	$38.75	$38.75	
BALER	ACRE	1.00	$7.50	$7.50	
IRRIGATION	ACRE	1.00	$63.50	$63.50	
TOTAL FIXED COSTS:				**$508.89**	
6. TOTAL COSTS:				**$4,728.54**	
7. NET RETURNS TO LAND, RISK, AND MANAGEMENT:				**$2,771.46**	

* CROP INSURANCE: 75% BASED PREMIUIM. NO DISASTER SUBSIDIES.

* PLEASE NOTE: THIS BUDGET IS FOR PLANNING PURPOSES ONLY, IT DOES NOT INCLUDE LAND RENT



NC STATE UNIVERSITY

TOBACCO - HAND HARVEST

PER ACRE MACHINERY AND LABOR REQUIREMENTS FOR HAND HARVEST TOBACCO

MONTH	OPERATION	TIMES OVER	LABOR HOURS	MACHINE HOURS	VARIABLE COSTS	FIXED COSTS
11,3	HEAVY DISK 20'	5.00	0.55	0.50	$18.15	$18.45
3	TOBACCO BEDDER 4-ROW	2.00	0.35	0.32	$3.66	$3.20
4	TOBACCO BED SHAPER 4-ROW	1.00	0.18	0.16	$1.73	$1.41
4	TOBACCO TRANSPLANTER 4-ROW	1.00	13.85	0.88	$23.51	$15.06
4,5	CULTIVATOR 4-ROW	5.00	1.27	1.15	$15.55	$11.35
3 thru 8	HIBOY	11.00	1.36	0.33	$24.97	$39.49
7,8,9,	TOBACCO TRAILER	4.00	2.15	10.32	$80.20	$108.04
9	BUSHHOG 14'	1.00	5.36	0.15	$1.69	$2.14
PER ACRE TOTALS FOR SELECTED OPERATIONS			25.07	13.81	$169.46	$199.14

CHEMICAL USE ASSUMPTIONS FOR HAND HARVEST TOBACCO

	UNIT	QUANTITY	PRICE OR COST/UNIT	TOTAL PER ACRE	MONTH
HERBICIDES & FUNGICIDES:					
SUCKER CONTROL:					
O-Tac	GAL	14.00	$22.63	$316.82	JUL AUG
INSECTICIDES:					
Dipel	LBS	5.00	$11.80	$59.00	
Grandevo	LBS	1.00	$26.00	$26.00	
Biological Controls					
FUNGICIDES:					
TOTAL:				$401.82	

Prepared by: S. Gary Bullen
North Carolina State Universtiy, Dept. Agricultural and Resource Economics

Petition Justification Statement “Continued”

Sucker Control/ Efficacy on Tobacco

A historical perspective for methods in controlling tobacco suckers is provided in the report below entitled “Historical Information” by Roland Cargill that discusses the trend from hand suckering, then the use of mineral oil or soybean oil, and finally the use of fatty alcohol product such as O-TAC.

HISTORICAL INFORMATION

By: Roland Cargill

In the late 1940s all topping and suckering was done by hand and required about 34 man-hours per Acre.[6]┘

Topping, worming and suckering were all done by hand. “As recalled by Billy Yeargin from his boyhood on a tobacco farm.”[5]┘

Suckers, branches that a tobacco plant likes to sprout and which take energy away from the leaves that the farmer wants to harvest normally are treated in conventional farming with a chemical that burns the suckers off when it starts to emerge. It is sprayed from a tractor. In organic tobacco fields, the farmer drips cooking oil on the sucker branches.

It has the same effect as the chemical, but must be done by hand, plant by plant, because the oil won’t go through a sprayer.

Early topping to improve yield and quality is usually done by hand. Suckers can be removed by hand as well as stunted by carefully applying approved soybean or mineral oil to the top of the plant. The farmer must be sure the oil runs down the stalks and into each leaf axil to get good control.

“Topping and suckering are the most time-consuming tasks associated with growing organic tobacco,” according to Ben Williamson (South Carolina farmer). [3]┘

“Sucker control requires the biggest adjustment for farmer’s according Micon Brown, one of the principles in Organic Smoke, Inc., since they can’t use the systemic sucker control agent maleic hydrazide. Much of the sucker control has to be done by hand, although these are some materials that have been revised from the old days (pre-MH). We base control of suckers on the use of old fashioned methods like applications of soy oil, vegetable oil or flax oil” he said. “They have to be hand applied. If the application is good, we get excellent sucker control, but you can also get leaf drop. And if the farmer applies it with too heavy a hand, it may kill the plant. [1]┘

“Organic production is quite a challenge and requires much more labor than conventional tobacco, “according to Aaron Sink, a High Point, N.C. grower.

There were no sucker control chemicals until recently, he says. “But now we have O-TAC. It has worked very well, just like any other contact chemical. We have to spray weekly and not get behind, but it has definitely cut back on the labor of controlling suckers. But you do still have to clean up by hand sometimes.”[4]

Sucker control has been an enormous problem for organic tobacco in the past, with most of it having to be done by hand. But for the last two seasons, Santa Fe growers have had an effective option. O-TAC PLANT CONTACT AGENT, a new contact sucker control agent developed by Santa Fe and Fair Products, Inc., was approved for use in organic programs in late 2009. In extension testing in North Carolina at the time, the results from use of the fatty alcohol product were similar to other sucker control products, said Loren Fisher, NC Extension Tobacco Specialist. “It doesn’t appear that a farmer would lose any control by using it. O-TAC PLANT CONTACT AGENT looks like a good fit in organic tobacco or in any program where you are trying to reduce or eliminate the use of MH.”[2]

References

[1] A New Day Dawns for Organic Tobacco by Chris Bickers, Tobacco International- September 2008.

[2] The Natural Way by Chris Bickers Tobacco Reporter April 1, 2012.

[3] Organic Tobacco Growing in America by Mike Little and Fielding Daniel, Mark Smith and Jim Haskins

[4] Organic Tobacco Opens Doors for North Carolina Grower by Chris Bickers, October 28, 2011 Southeast Farm Press.

[5] North Carolina Tobacco by Bill Yeargin (Historian) 2008.

[6] Mechanization and Labor Reduction A History of Flue-Cured Tobacco Production, 1950 to 2008 by Larry M. Sykes.

Petition Justification Statement”Continued”

Sucker Control / Efficacy on Tobacco

The Article “Fatty Alcohols vs Mineral oil(s)” describes the advantages of using fatty alcohols for sucker control and reduction in man hours of labor.

Efficacy

By: Roland Cargill

Fatty Alcohol vs mineral oil(s)

Soybean oil, vegetable oils mineral oils must be applied by hand directly down the stalk or to each leaf axel; if the mineral oil should happen to come in contact with the leaf it will cause the area covered to be burned and become a loss in harvesting. Since oil and emulsions flow rapidly to the ground line of the plant, there has been observed frequent severe rotting, particularly under moist conditions, as well injury to the leaf axils and stalks resulting in an increase in the plant susceptibility to disease.

Tests in 1950 with “Clip Oil” sucker controller the time to top and apply mineral oil with this device to an acre of tobacco was reduced by 3 ½ hours. [1]

The use of a spray emulsion of O-TAC PLANT CONTACT AGENT applied broadcast over the top of tobacco by machine spray further significantly reduces the man hours of labor required and will not result in leaf injury to the tobacco crop, and does not increase the susceptibility of the plant to diseases.

Reference:

[1] The Clip-Oil for Controlling Tobacco Suckers. Information Series No. 3 Special Issue to Industry. Department of Agricultural Engineering, North Carolina Agricultural Experiment Station.

Petition Justification Statement”Continued”

Efficacy “Continued”

2018 North Carolina State University Sucker Control Tests Oils vs Organic Fatty Alcohol at the Rocky Mount Research Station, NC and the Oxford Tobacco Research Station, NC

Petition Justification Statement”Continued”

Efficacy “Continued”

College of Agriculture & Life Sciences
Department of Crop & Soil Sciences cals.ncsu.edu/crop-and-soil-sciences

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NC STATE
UNIVERSITY

Introduction

The injury potential and efficacy of chemical alternatives to organic fatty alcohol for tobacco sucker (axillary bud) control are not presently known. The objectives of this study were to: 1.) evaluate a wide range of organic compounds for sucker control efficacy, 2.) determine the injury potential associated with each compound relative to harvestable leaves, and 3.) quantify these effects to cured leaf yield and quality.

Materials & Methods

Experiments were initiated in 2018 at the Upper Coastal Plain Research Station (UCPRS) near Rocky Mount, North Carolina and the Oxford Tobacco Research Station (OTRS) in Oxford, North Carolina. Treatments were arranged in a randomized complete block design and were replicated three times at the UCPRS and four times at the OTRS. Experimental units consisted of a single treated row measuring four feet wide and 50 feet long. Planting density was 6,000 plants/acre in both environments. Tobacco was produced using recommendations from Fisher (2018), with the exception of treatments imposed.

Treatment application was initiated three days prior to flower removal and were followed with sequential applications occurring every five days, where possible. A list of suckercide active ingredients and application rates are presented in Table 1. Each suckercide was delivered using two methods, traditional foliar applications (3-nozzle boom) and drop line applications (single nozzle, focused down-stalk). Foliar applications were delivered with a CO_2-pressurized backpack sprayer calibrated at a delivery volume of 50 gallons/acre using a standard 20-inch, three nozzle boom that contained a TG3-TG5-TG3 nozzle arrangement. Drop line applications were also delivered with a CO_2-pressurized backpack sprayer calibrated to deliver 30 mL solution per plant. In total, six applications were delivered within each treatment combination.

Data Collection

Visual plant injury ratings were collected immediately prior to applications two, three, and six using a scale of 0-10. Within this rating system, 0 indicates the absence of plant injury and 10 represents complete plant death. Three weeks following the sixth suckercide application sucker development was quantified. All suckers from five plants within each row were removed, counted, and weighed while green using the methods outlined by Yelverton et al. (1993).

Petition Justification Statement”Continued”

Efficacy “Continued”

Data Analysis
Data were subjected to ANOVA using the PROC Mixed procedure in SAS version 9.4. Results were pooled across both research sites for all parameters (except for leaf quality) in order to improve the power of conclusions drawn. Treatment was considered as a fixed factor, whereas growing environment and replication were considered as random factors. Treatment means were reported using least square means. Means were separated using Fisher’s protected LSD at P≤0.05.

Results & Discussion
Injury. Leaf injury was greatest in treatments comprised of pelargonic acid, with the broadcast application resulting in greater injury than the drop line application (Table 2). Leaf injury from pelargonic acid broadcast treatments ultimately eliminated the top three to five harvestable leaves. Leaf injury declined by approximately 50% with the drop line application of pelargonic acid due reduced leaf area exposure to the active ingredient. Despite this observation, injury with the drop line application was still in excess of what would be acceptable to commercial producers. Previous research has indicated that pelargonic acid is extremely injurious to flue-cured and burley tobacco, even when applied in a solution concentration as low as one percent (Matthew Vann, unpublished data). Leaf injury in all other treatments evaluated in this study were generally less than 1.0 (Table 1).

Sucker Growth. Sucker number per plant was similar among the non-treated control, vegetable oil (broadcast and drop line), and canola oil (broadcast and drop line) treatments (Table 3). Peppermint + spearmint oil (broadcast and drop line) slightly reduced the number of suckers per plant; however, control was still considered to be minimal (Table 3). Treatments comprised of fatty alcohol and pelargonic acid produced the lowest number of suckers per plant, regardless of application method (Table 3). Similar trends were observed when sucker mass per plant was quantified (Table 3).

Percent Control. Sucker control was greatest in treatments containing fatty alcohol (>98%) and pelargonic acid (82-98%). Results were similar when broadcast and drop line applications were compared within each of those materials (Table 3). Despite presenting good to excellent sucker control, the presence of leaf injury was far too great in pelargonic acid treatments to receive consideration for commercial applications (Table 2). Sucker control was greatly reduced in programs comprised of peppermint + spearmint oil (32-33% control) and canola oil (9-15%) (Table 3). However, control resulting from peppermint + spearmint oil and canola oil was statistically better than that documented in with vegetable oil when compared to the non-treated control (Table 3).

Post-harvest Measurements. Cured leaf yield, quality, and value were greatly impacted by treatments imposed (Table 4). Cured leaf yield and value were maximized in treatments comprised of fatty alcohol, irrespective of application method. The same observation was documented for crop quality at the Oxford Tobacco Research Station (Table 4). All other treatments resulted in similar yield and value to the non-treated control, which was absent of chemical suckercide application. This trend is indicative of poor sucker control following the application of vegetable oil, canola oil, and peppermint + spearmint oil and extreme leaf injury following pelargonic acid application. In addition, cured leaf quality was reduced by pelargonic acid applied with a 3-nozzle boom at the Upper Coastal Plain Research Station (Table 4). The reduction in cured leaf quality within this treatment can be attributed to severe chemical injury, which also reduced cured leaf yield and value (Table 4). It should be further emphasized that total yield and value were significantly reduced following the application of every active ingredient evaluated in this study except for fatty alcohol, which adds great concern to their application in the commercial production of organic flue-cured tobacco due to the dramatic reduction in farm gate income.

Conclusions

Based on the observations to date, chemical alternatives to fatty alcohol for organic sucker control appear to have limited efficacy when applied at concentrations utilized in this study. Furthermore, the injury potential for the only product aside from fatty alcohol to provide an acceptable level of sucker control (pelargonic acid) was far too great to recommend for commercial use. Measurements pertaining to cured leaf yield and value reinforce these concerns, as both parameters were reduced by vegetable oil, canola oil, pelargonic acid, and peppermint oil + spearmint oil. Alternatively, percent sucker control and cured leaf yield, quality, and value were maximized in treatments comprised of fatty alcohol, regardless of application method.

References

Fisher, L.R., editor. 2018. 2018 North Carolina State University Flue-cured Tobacco Production Guide (AG-187 (Revised)). North Carolina Cooperative Extension Service, Raleigh, NC.

Fisher, L.R., M.C. Vann, and K. Barnes. 2018. Selecting a variety. In L.R. Fisher (ed.) 2018 North Carolina State University Flue-cured Tobacco Production Guide (AG-187 (Revised)). North Carolina Cooperative Extension Service, Raleigh, NC. p. 15-39.

Yelverton, F.H., D.T. Gooden, T.D. Reed, M.G. Stephenson, and E.B. Whitty. 1993. The effects of butralin on sucker control in flue-cured tobacco. Tobacco Science 37:54-58.

Petition Justification Statement”Continued”

Efficacy “Continued”

Table 1. Suckercide treatments, active ingredient, application concentration, and manufacturer.

Suckercide Active Ingredient	Trade Name	Application Rate†	Manufacturer
		% v/v	
85% Fatty Alcohol	O-Tac	4,5,5,5,5,5	Fair Products
680 g/L Pelargonic Acid	Pelargonic Acid	4,5,5,5,5,5	Belchim Crop Protection
93% Vegetable Oil	Natur’l Oil	4,5,5,5,5,5	Stoller USA
100% Canola Oil	Canola Oil	4,5,5,5,5,5	Atlantic Organic
5% Spearmint + 5% Peppermint Oil	Sucker Zap	3,4,4,4,4,4	Excel Ag, Corp.

† Sequential applications were delivered on a five day spray rotation, increased application concentrations were utilized for application numbers two through six.

Petition Justification Statement”Continued”

Efficacy “Continued”

Table 2. Flue-cured tobacco injury following suckercide application one, two, and five[†]. Data are pooled across two growing locations.

Suckercide and (application method)	5 DAT	10 DAT	25 DAT
	——Visual Rating[‡]——		
Topped, Not Suckered	0.00 c	0.00 d	0.00 c
Fatty alcohol (3-nozzle boom)	0.12 c	0.26 cd	0.34 c
Fatty alcohol (Drop Line)	0.54 c	0.41 cd	0.22 c
Pelargonic Acid (3-nozzle boom)	4.50 a	5.77 a	7.00 a
Pelargonic Acid (Drop Line)	2.50 b	3.12 b	3.62 b
Vegetable oil (3-nozzle boom)	0.00 c	0.12 cd	0.26 c
Vegetable oil (Drop Line)	0.00 c	0.26 cd	0.07 c
Canola Oil (3-nozzle boom)	0.12 c	0.12 cd	0.00 c
Canola Oil (Drop Line)	0.39 c	0.56 c	0.00 c
Peppermint + Spearmint Oil (3-nozzle boom)	0.00 c	0.05 cd	0.17 c
Peppermint + Spearmint Oil (Drop Line)	0.25 c	0.19 cd	0.03 c

[†] **Treatment means followed by the same letter within the same column are not significantly different at the $\alpha=0.05$ level.**

[‡] **Visual injury assessed on a scale of 0-10, with 0 being absent of injury and 10 representing complete plant death.**

Petition Justification Statement”Continued”

Efficacy “Continued”

Table 3. Sucker number per plant, mass per plant, and percent control following sequential suckercide applications†. Data are pooled across two growing locations.

Suckercide and (application method)	Count	Mass	Control
	number/plant	ounces/plant	%
Topped, Not Suckered	5.02 a	26.08 a	0.00 d
Fatty alcohol (3-nozzle boom)	0.44 c	0.00 c	98.8 a
Fatty alcohol (Drop Line)	0.09 c	0.00 c	99.1 a
Pelargonic Acid (3-nozzle boom)	1.08 c	3.97 c	82.8 a
Pelargonic Acid (Drop Line)	0.28 c	0.15 c	98.0 a
Vegetable oil (3-nozzle boom)	5.15 a	24.93 a	-3.3 d
Vegetable oil (Drop Line)	4.74 a	26.13 a	7.1 cd
Canola Oil (3-nozzle boom)	4.73 a	21.37 ab	14.8 b-d
Canola Oil (Drop Line)	5.19 a	22.24 ab	9.2 b-d
Peppermint + Spearmint (3-nozzle boom)	3.81 ab	17.09 b	32.4 bc
Peppermint + Spearmint (Drop Line)	3.10 b	16.53 b	33.7 b

† Treatment means followed by the same letter within the same column are not statistically different at the α=0.05 level.

Petition Justification Statement”Continued”

Efficacy “Continued”

Table 4. Cured leaf yield, quality, and value following sequential suckercide applications[†]. Data are pooled across two growing locations, unless otherwise noted.

Suckercide and (application method)	Yield	Quality[‡]		Value[§]
	lbs./acre	OTRS[§§]	UCPRS	$/a
Topped, Not Suckered	1,617 b	68 cd	84 a	2,552 b
Fatty alcohol (3-nozzle boom)	2,759 a	85 a	84 a	4,826 a
Fatty alcohol (Drop Line)	2,641 a	84 a	82 a	4,473 a
Pelargonic Acid (3-nozzle boom)	1,212 b	67 cd	68 b	1,692 b
Pelargonic Acid (Drop Line)	1,624 b	82 ab	86 a	2,732 b
Vegetable oil (3-nozzle boom)	1,439 b	61 d	81 a	2,111 b
Vegetable oil (Drop Line)	1,610 b	73 bc	84 a	2,587 b
Canola Oil (3-nozzle boom)	1,457 b	65 cd	82 a	2,213 b
Canola Oil (Drop Line)	1,603 b	67 cd	84 a	2,558 b
Peppermint + Spearmint (3-nozzle boom)	1,513 b	66 cd	79 a	2,279 b
Peppermint + Spearmint (Drop Line)	1,813 b	68 cd	82 a	2,814 b

[†] Treatment means followed by the same letter within the same column are not statistically different at the α=0.05 level.

[‡] Quality is assessed on a scale of 1-100, with 100 being of the highest quality.

[§] Value estimates reflect conventional tobacco prices as reported by Fisher et al., 2018 and are used to express treatment implications to farm gate revenue.

[§§] OTRS, Oxford Tobacco Research Station in Oxford, NC; UCPRS, Upper Coastal Plain Research Station near Rocky Mount, NC.

Petition Justification Statement”Continued”

Sucker Control / Efficacy on Tobacco

RIGHT TIME FOR FIRST SPRAY IS WHEN 5 to 10% OF THE PLANTS ARE CHEMICALLY TOPPED

By W. K. Collins

The best time, actually the best stage of growth, to begin to spray your contact sucker control product is very early in the button stage of plant development. This stage often varies greatly on a given farm just as genera growth varies.

The best stage of growth is when the plants have all of the leaves they will ever have - this is the pre-button stage. Starting to spray followed by early topping will give you the most benefits compared to starting the job later.

Tobacco plants undergo several stages of above-ground growth. After plants establish a root system, the plants begin to add leaves on the stalks with growth emphasis on leaf development. This is known as the vegetative stage. Then, in about 60 days, the growth emphasis changes to the reproductive stage as shown by the button development also known as the sexual stage of making seed. Major plant resources go to developing seed which is just opposite of leaf development. Every day the button (top) remains on plants, the potential yield per acre is reduced one percent over the next 3-4 weeks or about 25 pounds per acre per day!

When the button or later floral stage is removed, suckers immediately start to develop and must be controlled to obtain the numerous benefits of early topping and sucker control that will be provided later in the article. Until removed, the top suppresses sucker development.

The big thing we want to happen with early topping and sucker control is to shift the plants back to the leaf development stage and development of upper leaves that bring the highest prices. We are fortunate that the tobacco plant would like to grow until frost kills it and the shift can be made. Seed crops die after seed set and do not have the luxury of continued growth.

There are two sucker buds in every leaf axil and maybe a third sucker on vigorous crops or 40-50 suckers per plant. This makes suckers the biggest pests in tobacco production because they are on every plant, in every field, every year! No other pests are so prevalent.

Efficient application of your contact solution must occur in your sucker control and topping program to obtain maximum benefits.

When to Start

Plants should be sprayed before topping to kill the suckers when the solution wets them. The mode of action is that the contact solution pulls water from the tender sucker tissue faster than the plant can replace the water and not materially injuring the more developed leaf tissue. The sucker is killed by dehydration of the suckers that are wetted by the spray solution. The smaller the suckers are, the more tender they are, and the easier they are killed.

We normally believe that a 4% concentration of the contact solution may be adequate for the first spraying before topping. The "tops" should be on the plants when the first spraying is done. The top intercepts the spray pattern to start the solution rundown to the soil line. It has been found that 50 gallons of spray solution per acre are required for complete rundown to the soil line as seen by wet soil at the base line.

The concentration of the spray solution is critical to obtain the kill of the primary and secondary sucker which is really just a bump or small group of cells just behind the primary sucker in each leaf axil.

Even under best conditions additional contact applications should be made 3-5 days after the first applications with no less than a 5% concentration.

<u>You should try concentrations higher than 4% on the first application. You should apply higher concentrations to obtain chemical topping of 5-10% of the plants</u>. This will also cause a very high degree of sucker control. If this causes leaf drop, most likely this is associated with excess available nitrogen. Excess nitrogen promotes excess sucker growth from the third sucker in each leaf axil. A little leaf drop may not be as big a problem as the excess sucker growth.

Some leaf burn or "sting" may occur but tobacco has a tremendous capacity to compensate for so-called loss time. The big loss is about 25 pounds per day per acre by not topping.

If leaf drop is observed, be sure to barn dry tobacco and exhaust as much air the cure will permit. Experience has shown that most leaf burn with contact solutions occur when applied at pump pressures higher than 20 psi or the contact solution is not constantly agitated in the spray tank. The alcohol in the product is lighter than water. The alcohol floats to the top within the spray tank. When this "solution" is sprayed, there is limited sucker control where mainly water is sprayed and a varying degree of leaf burn as the solution level in the spray tank reaches the bottom and becomes more concentrated. The degree of sucker control also increases to nearly 100% where there is some leaf burn. The contact, O-Tac, has been sprayed at a low pump pressure (20 psi) at the Oxford Tobacco Research Station up to 10% without leaf burn. The sucker control was close to 100%.

Advantages of Early Topping

1. Yield increases about 1% per day or 25 pounds per day over a three-week period. The loss of harvesting lower leaves could largely be offset by topping earlier than previously.
2. The topping job is done before harvest begins.
3. The chances of plants being blown over are reduced.
4. The habitat for some insects is eliminated. Nicotine build-up starts when the plants are topped-most insects do not like nicotine which discourages buildup.
5. Helps plants withstand drought.

Petition Justification Statement"Continued"

Sucker Control / Efficacy on Tobacco

II. Describe any nonsynthetic substances, synthetic substances on the National List, or Alternative cultural method that could be used in place of the petitioned synthetic substance.

Manual topping and suckering is labor intensive, but does not involve the use of any chemicl substance. Mineral oil, cooking oil or paraffin oil are currently the only topping and suckering substances used by organic crop producers (Little et al., 2008). Fatty alcohols are used independently of other topping and suckering chemcicals. There is no known interaction between the fatty alcohols that might be used for topping and suckering (Calvert, 1953)

Petition Justification Statement"Continued"

Sucker Control / Efficacy on Tobacco

Efficacy

According to the North Carolina Department of Agriculture, "based on information provided by North Carolina State University's tobacco research and Extension faculty, effective alternatives to fatty alcohols approved for use on organic tobacco do not exist. Alternatives such as mineral oil must be applied by hand, increase worker exposure, and do not provide acceptable level of sucker control, resulting in additional yield and quality losses. Survey of organic tobacco growers suggest that the loss of effective sucker control products would reduce acreage due to sharp increase in labor and losses in yield and quality."

Petition Justification Statement”Continued”

III. Describe the beneficial effects to the environment, human health, or farm ecosystem from use of synthetic substance that support its use instead of the use of nonsynthetic substance or alternative cultural method.

Economics

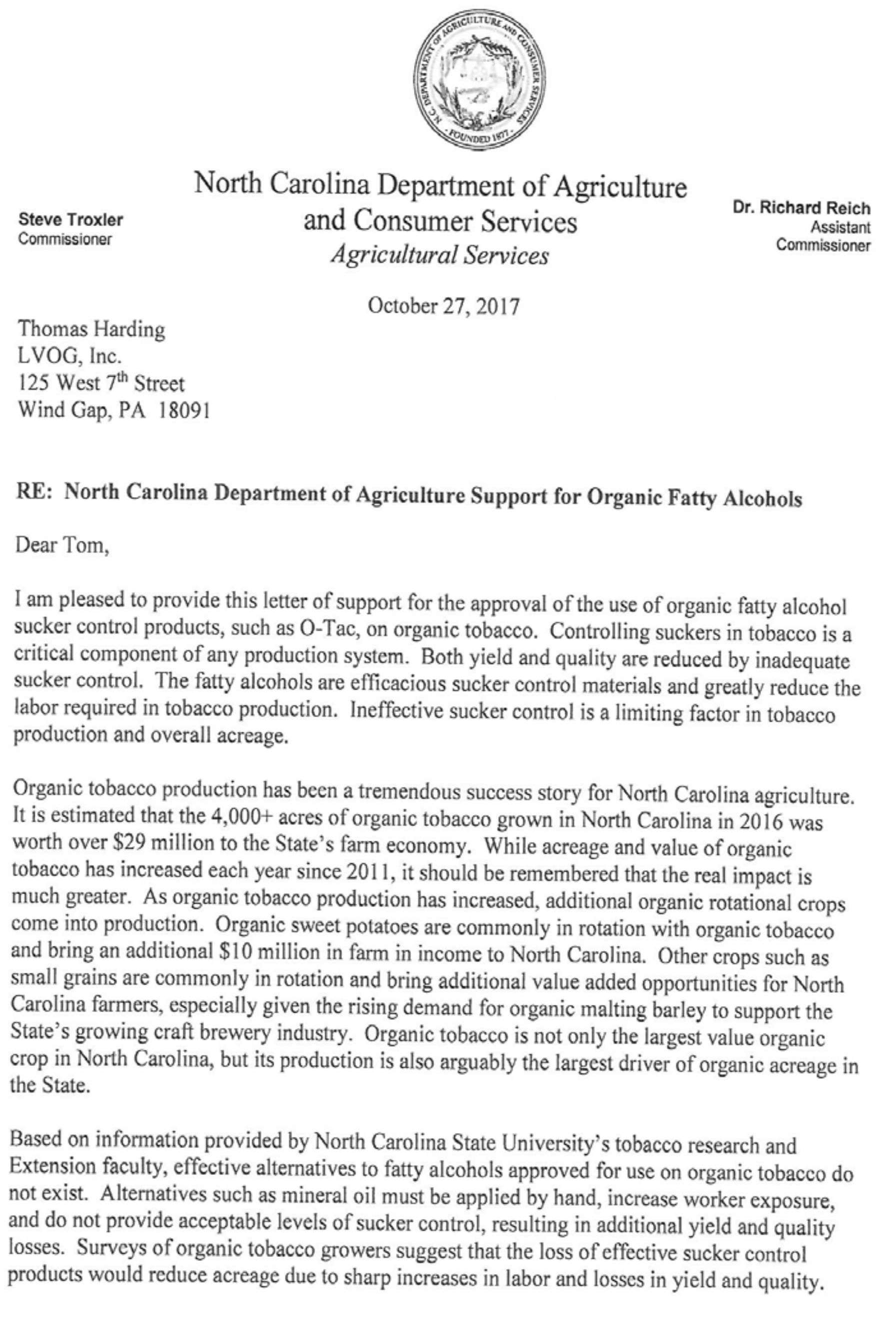
According to the North Carolina Department of Agriculture, “organic tobacco production has been a tremendous success story for North Carolina agriculture. It is estimated that the 4000+ acres of organic tobacco grown in North Carolina in 2016 was worth over $29 million to the State’s farm economy. While acreage and value of organic tobacco has increased each year since 2011, it should be remembered that the real impact is much greater. As organic tobacco production has increased, additional organic rotational crops come into production. Organic sweet potatoes are commonly in rotation with organic tobacco and bring an additional $10 million in farm income to North Carolina. Other crops such as small grains are commonly in rotation and bring additional value added opportunities for North Carolina farmers, especially given the rising demand for organic malting barley to support the states growing Craft Brewery industry. Organic tobacco is not only the largest value organic crop in North Carolina, but its production is also arguably the largest driver of organic acreage in the State.”

Petition Justification Statement”Continued”

Economics “Continued”

According to Dr. Loren Fisher it is estimated that in additional 30 hours of labor per acre are required to manage suckers without using a fatty alcohol, or an additional labor cost of $338.00 per acre. It is also estimated that there is an additional 5 - 8% ($375.00 to $600.00 per acre) loss in tobacco value from reduced yield and quality due to poor sucker control.

It is estimated that O-TAC (fatty alcohols) is used on approximately 20,000 acres (estimated 500+ Farm families) across the tobacco producing states in the US. Approximately ⅓ of the farms where O-TAC is used are producing certified organic tobacco with the remainder producing pesticide residue free tobacco. Acreage of organic tobacco has dramatically increased since the registration of O-TAC (fatty alcohols) as growers employed this effective sucker control measure which reduced management costs and allowed for expansion of organic production without substantially increasing labor inputs.



North Carolina Department of Agriculture
and Consumer Services
Agricultural Services

Steve Troxler
Commissioner

Dr. Richard Reich
Assistant
Commissioner

October 27, 2017

Thomas Harding
LVOG, Inc.
125 West 7th Street
Wind Gap, PA 18091

RE: North Carolina Department of Agriculture Support for Organic Fatty Alcohols

Dear Tom,

I am pleased to provide this letter of support for the approval of the use of organic fatty alcohol sucker control products, such as O-Tac, on organic tobacco. Controlling suckers in tobacco is a critical component of any production system. Both yield and quality are reduced by inadequate sucker control. The fatty alcohols are efficacious sucker control materials and greatly reduce the labor required in tobacco production. Ineffective sucker control is a limiting factor in tobacco production and overall acreage.

Organic tobacco production has been a tremendous success story for North Carolina agriculture. It is estimated that the 4,000+ acres of organic tobacco grown in North Carolina in 2016 was worth over $29 million to the State's farm economy. While acreage and value of organic tobacco has increased each year since 2011, it should be remembered that the real impact is much greater. As organic tobacco production has increased, additional organic rotational crops come into production. Organic sweet potatoes are commonly in rotation with organic tobacco and bring an additional $10 million in farm in income to North Carolina. Other crops such as small grains are commonly in rotation and bring additional value added opportunities for North Carolina farmers, especially given the rising demand for organic malting barley to support the State's growing craft brewery industry. Organic tobacco is not only the largest value organic crop in North Carolina, but its production is also arguably the largest driver of organic acreage in the State.

Based on information provided by North Carolina State University's tobacco research and Extension faculty, effective alternatives to fatty alcohols approved for use on organic tobacco do not exist. Alternatives such as mineral oil must be applied by hand, increase worker exposure, and do not provide acceptable levels of sucker control, resulting in additional yield and quality losses. Surveys of organic tobacco growers suggest that the loss of effective sucker control products would reduce acreage due to sharp increases in labor and losses in yield and quality.

For the above reasons, we support the approval of organic fatty alcohol sucker control products in organic tobacco. They are critical to sustaining and continuing to grow not only North Carolina's organic tobacco acreage, but also the acreage and production of other organic crops. Please feel free to contact us if you have any questions.

Sincerely,

Richard C. Reich

Richard C. Reich, Ph.D.
Assistant Commissioner of Agriculture
NCDA&CS

E-mail: Richard.Reich@ncagr.gov
1001 Mail Service Center, Raleigh, North Carolina, 27699-1001 (919) 707-3015 • Fax (919) 733-1141
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Petition Justification Statement”Continued”

Labor Savings

According to Dr. Loren Fisher, Department of Crop and Soil Sciences N.C State University; “EPA registration of sucker control chemicals in conventional production systems is widely considered one of the most important developments that allowed growers to reduce labor inputs from 600 man hours /acre down to approximately 60 man hours/ acre in the last 50 years”

“Prior to the registration of O-TAC (fatty alcohols) for sucker growth suppression in organic tobacco, growers did not have any viable and effective options for acceptable chemical control of suckers growth compared to conventional growers. Growers had to employ ineffective chemical control measures, such as mineral oil, soybean oil and other vegetable oils and then remove suckers by hand, which resulted in a high labor requirement and reduced yield.

In many cases, growers reported applying mineral oil (or related products) by “hand” with backpack because alternatives to fatty alcohols were not effective when applied by mechanical sprayers.” This method was extremely laborious and tedious and created undue exposure of labor to extreme working conditions. It is estimated that an additional 30 hours of labor per acre required to manage suckers without using fatty alcohol, or an additional labor cost of $338.00 per acre. It is also estimated that there is an additional 5 – 8% ($375.00 - $600.00 per acre) loss in tobacco value from reduced yield and quality due to poor sucker control.

Petition Justification Statement”Continued”

Environmental Impact

The Safer Chemical lngredients List (SCIL) lists chemical ingredients that EPA's Safer Choice Program has evaluated and determined to be safer than traditional chemical ingredients. This list was designed to help manufacturers find safer chemical alternatives to meet the criteria of the Safer Choice Program. Safer Choice decides to include a chemical on the SCIL based on the hazard information from a broad set of resources, including the identification and evaluation of all available toxicological and environmental fate data. According to the Safer Choice determination of the EPA, 1-decanol, 1-octanol, 1-dodecanol and the C_6-C_{12} alcohols are expected to be of low concern based on experimental and modeled data.

Linear fatty alcohols in general are easily biodegradable. The solubility of fatty alcohols in water decreases with an increasing C-chain length. Fatty alcohols possess only moderate acute toxicity for aquatic organisms. In general, in their range of water solubility no toxic effects are observed. However, a number of studies were performed with concentrations that are considerably above the water solubility. Available data for fatty alcohols chronic toxicity do not indicate a special toxicological potential (Condea, 2000).

Fatty alcohols are recognized as High Production Volume (HPV) chemicals. Global production volume is estimated at over 1.9 million metric tons. Linear to slightly branched log chain alcohols ranging from 6 to 22 alkyl carbons (C) biodegrade exceptionally rapidly in the environment (half-lives on the order of minutes); however, due to continuous use and distribution to waste water treatment systems, partitioning properties, biodegradation of alcohol based surfactants and natural alcohol sources, linear chain alcohols are universally detected in waste water effluents. A large fraction of environmentally detected alcohols are naturally derived alcohol from animal, plant and microbiologically mediated biotransformation. The fatty alcohols from both natural and manufactured sources represent a low risk for environmental contamination (Belanger et al., 2009).

Petition Justification Statement”Continued”

Environmental Impact “Continued”

C_6-C_{12} fatty alcohols are likely to volatize quickly, however, longer chain alcohols (C>12) reaching water supplies are not expected to be hydrolytically degraded (EPA, 2007). The shorter chain fatty alcohols (C<12) are degraded by oxidation and hydrolysis (Patterson et al., 1970). In the atmosphere all C-H containing organic substances react with photochemically generated hydroxyl radicals. The half live for photodegradation of the fatty alcohols varies between 12 and 30 hours (measured for 1-hexanol). Fatty alcohols are biodegradable, and those above C_{11} may be considered potentially bioaccumulative. Alcohols act by non-polar narcosis. Any toxicity produced by the fatty alcohols with chain lengths less than12 is considered sub-acute with a fifty percent effective concentration (EC_{50}) ranging from 2.0 to 25 milligrams/liter (Fisk et al., 2009). The category comprises a homologous series of linear and essentially linear C_6- C_{22} alcohols. In addition catalysts such as sulfuric acid present an environmental issue (Condea, 2000).

Increasing carbon chain length leads to a predictable pattern in physico-chemical properties that drives a distinct range of fate behaviors in the environment. Fatty alcohols all have the same mode of ecotoxicological action. In addition, they are all rapidly biodegradable especially at environmentally relevant concentrations. Alcohols are metabolized/bio-transformed in living organisms suggesting that bioaccumulation potentials based on octanol-water partition coefficients are likely to be overestimated. Measured biological concentration factor (BCF) data on fatty alcohols supports the concept that the bioaccumulation potential of these substances will be lower than estimated from log Kow 1 -hexanol and 1- octanol present a greater hazard for the environment (high acute toxicity to fish, daphnids and algae, in the range 0.1-1mg/l, and/or high chronic toxicity). The substances in this subgroup biodegrade rapidly and environmental monitoring data from seven countries indicates exposures to the environment is anticipated to be low (OECD, 2006).

Available toxicity data indicate that aliphatic alcohols are "practically non-toxic" to honey bees (acute contact LD50 > 25 µg/bee). However, given that aliphatic alcohols can be used as Lepidopteran sex inhibitors, there is a potential for sublethal (e.g., reproductive) effects on non-target Lepidopterans, such as butterflies. This potential effect cannot be quantified at this time (EPA, 2007).

Petition Justification Statement"Continued"

Human Health, Welfare and Safety

The use of fatty alcohols for sucker control in organic tobacco by mechanical spray means reducing the amount of worker exposure to "green tobacco" syndrome vs the several trips in the field to remove suckers by hand after the use of less effective products, such as mineral oil, soybean oil, etc., as well as hand- suckering. These methods are extremely laborious and tedious and create undue exposure of labor to extreme working conditions.

There is far less exposure from application or fatty alcohols by machine sprayers compared to hand application of less effective products such and mineral oil, soybean oil, etc.

Furthermore, toxicity data for the aliphatic alcohols consisting of acute toxicity, irritation, and sensitization studies, developmental rat (oral and inhalation) toxicity studies and a 90-day rat (dermal) study were evaluated for the Environmental Protection Agency (EPA) health risk determination. The available mutagenicity studies included the Ames, micronucleus, and gene mutation assays. Acute inhalation studies with the rat resulted in estimates of the median lethal dose (LD_{50}) above the limit concentration of 2 milligrams/Liter. However, eye irritation studies resulted in severe and sometimes non-reversible eye irritation. Dermal irritation studies revealed slight to moderate irritation in rabbits, and the aliphatic alcohols generally did not produce sensitization in tests with guinea pigs. There is no evidence to suggest that the aliphatic alcohols cause increased susceptibility in infants and children. Based on the results of the available studies, no endpoints of toxicological concern have been identified for human health risk assessment purposes. The EPA concluded that there are no human health risks of concern for aliphatic alcohols. Currently, there is no known mode of toxicological action for the aliphatic alcohols. Based on the low hazard concern via the oral, dermal, and inhalation routes of exposure, a quantitative risk assessment for the aliphatic alcohols was not found necessary (EPA, 2007).

Petition Justification Statement”Continued”

Human Health, Welfare and Safety “Continued”

Fatty alcohol products used for tobacco topping and suckering are of not very toxic following acute and repeated exposures. Although, skin and eye irritation are commonly observed. The mammalian metabolism of fatty alcohols used in tobacco topping and suckering is highly efficient. (Veenstra et al., 2009; OECD, 2006).

Aliphatic alcohols are absorbed by all common routes of exposure, widely distributed within the body and efficiently eliminated. There is a limited potential for retention or bioaccumulation for the parent alcohols and their biotransformation products. For the aliphatic alcohols in the range
$C_4 – C_{11}$ a potential for skin and eye irritation exists, without concerns for tissue destruction or irreversible changes. Typical findings include: slightly increased liver weight, in some cases accompanied by clinical chemical changes but generally without concurrent histopathological effects. Aliphatic alcohols do not have a potential for producing peroxisome proliferation. Central nervous system (CNS) effects were absent upon inhalation or dietary administration, however
1-hexanol and 1- octanol showed a potential for CNS depression upon repeated administration of a bolus dose. Similarly, 1- hexanol and 1-octanol induced respiratory distress upon repeated administration of a bolus dose. Aliphatic alcohols do not have a potential for peripheral neuropathy. Typical no observable adverse effects level (NOAEL) for aliphatic alcohols range from 200 mg/kg/ day to1000 mg/kg/day in the rat upon sub-chronic administration via the diet. There has not been evidence of a carcinogenic potential for aliphatic alcohols. They do not contain structural elements of concern for potential interaction with DNA and have been shown to be without mutagenic activity, primarily on the basis of Ames assays and mouse micronucleus assays (Nelson et al., 1990a; OECD, 2006).

On the basis of the lack of adverse findings in the reproductive organs in repeated dose toxicity studies and in screening studies for reproductive effects aliphatic alcohols are considered without a potential for adverse effects on fertility and reproductive toxicity. Similarly, developmental toxicity studies with aliphatic alcohols have confirmed the lack of potential adverse effects on the developing fetus.

Petition Justification Statement"Continued"

Essentiality

Essentiality Of Fatty Alcohols

Please reference herein all *New and Additional Research Studies, Trials, and Reports*, science based which proves, suggested Alternative Materials, natural and/or synthetic materials on the National List are **NOT EFFECTIVE** sucker controls for use on organic tobacco crops. Please carefully review the Academic Studies and Field Trials from NCSU, etc.! Please read the TAP.

Furthermore, the economic benefits from the Use of Fatty Alcohols on Organic Tobacco Crops are proven and substantial, and therefore must be valued and considered when reviewing and approval of any *Material Tools to on the National List*. **Fatty Alcohols** are a proven and clear choice.

Fatty Alcohols provide serious economic, environmental, health and safety, and cultural benefits to the organic tobacco farming system, which includes soil health, biodiversity, serious crop rotations, and farm transitions to organic. And the benefits of poly-cultures and additional cash crops; sweet potato, small grains, forages, etc.

The **Use of Fatty Alcohols** provides essential product quality benefits, increased farm gate prices, and quality incentives that further benefit the organic family farm, farmworkers, and their rural communities, and helps keep the next generation on a certified farm. Remember, most of this land has been growing tobacco for several decades, *now it is certified organic*!

Most importantly, when considering NOSB Approval for the Use of Fatty Alcohols on Organic Tobacco Crops, please reference and carefully review all elements of the previous **TAP Review**. It clearly points out that **Fatty Alcohols Meet ALL** required aspects of a petitioned material to be approved for the use on organic crop production. Coupled with the scientific field trials performed by **NCSU** and grower testimony makes Fatty Alcohols the best choice and an essential tool for sucker control for organic tobacco farmers.

Lastly, it must be said, the OFPA/NOP does not discriminate relative size and scale or crop type, or use; therefore, in full transparency of organic tobacco crop farming, may not be a favorable organic crop of choice for some? Please do remember, the final choice is actually the **CONSUMERS CHOICE**!

We believe all organic crops and the materials used must be considered without a bias and within full transparency, whereas organic tobacco farmers provide an alternative product choice to the consumer in a growing organic marketplace that requires the best and cleanest choice possible - let the consumer have this vital organic option, and have a clear organic choice!

The **Use of Fatty Alcohols On Organic Tobacco Cr**ops is the best and most effective choice for the organic tobacco farmer to continue to provide the highest quality organic choice to a growing market that requires choice and product authenticity!

Petition Justification Statement”Continued”

Summary

Proper crop use of these *Fatty Alcohols* reduces overall insect/pest pressures and chemical use, farm labor exposure, farm labor cost and energy. Through carefully timed applications as required, it reduces crop hand topping and suckering, this activity benefits the overall farm resources management, during the pre-and- post harvest peiords.

When used in conjuinction with traditional cultural practices, *Fatty Alcohols,* increases crop yield, quality and marketability and has been shown to increase gross yield by several hundreds pounds per acre, with a substandial income increase in crop value for the farmer!

Additionally, clean sucker and foliage control enables machine harvesting, once again increasing crop yield and quality, and providing major energy and labor savings. Following are a few benefits realized by the farmer when using *Fatty Alcohols:*

- **Yield increases amounting to 20-25 pounds per acre, per day.**
- **Pest/insect population reductions.**
- **Labor and chemical use reduction.**
- **Time/cost savings at critical pre-post–harvest handling.**
- **Increase crop quality and yields and gross income margins to the farmer.**

In summary, the proper use of *Fatty Alcohols* on organic tobacco, increases crop quality, yield, and value-added components, at substantial labor and energy reductions, which contribures significantly to the farm gross/net income of the family farm unit!

Petition Justification Statement"Continued"

Endorsement

"Successful organic tobacco production includes management tools such as O-TAC PLANT CONTACT AGENT. For the above reasons, we support approval of natural fatty alcohol Sucker Control products in organic tobacco production. They are critical to sustaining and continuing to grow not only North Carolina's organic tobacco acreage, but also the acreage and production of other organic crops."

Steve Troxler
Commissioner

North Carolina Department of Agriculture
and Consumer Services
Agricultural Services

Dr. Richard Reich
Assistant Commissioner

January 18, 2018

Secretary Sonny Perdue
U.S. Department of Agriculture
1400 Independence Ave., S.W.
Washington, DC 20250

Dear Secretary Perdue:

I am pleased to provide this letter of support for the approval of natural fatty alcohol sucker control products, such as O-Tac, for organic tobacco production. Controlling suckers in tobacco is a critical component of our production system. Both yield and quality are reduced by inadequate sucker control. The fatty alcohols are efficacious sucker control materials and greatly reduce the labor required in tobacco production. Ineffective sucker control is a limiting factor in tobacco production and overall acreage.

Organic tobacco production has been a tremendous success story for North Carolina agriculture. It is estimated that the more than 4,000 acres of organic tobacco grown during 2016 was worth over $29 million to our state's farm economy. While acreage and value of organic tobacco has increased each year since 2011, it should be remembered that the real impact is much greater. As organic tobacco production has increased, additional organic rotational crops come into production. Organic sweet potatoes are commonly in rotation with organic tobacco and bring an additional $10 million in farm income to our state. Other crops, such as small grains, are commonly in rotation and bring additional value-added opportunities for our farmers, especially given the rising demand for organic malting barley to support the state's growing craft brewery industry. Organic tobacco is not only the largest value organic crop in North Carolina, but its production is also arguably the largest driver of organic acreage in the state.

Based on information provided by North Carolina State University's tobacco research and extension faculty, effective alternatives to fatty alcohols approved for use on organic tobacco currently do not exist. Alternatives such as mineral oil must be applied by hand which increases worker exposure and does not provide acceptable levels of sucker control. Surveys of organic tobacco growers suggest that without effective sucker control products, acreage would decline due to the sharp increases in labor along with losses in leaf yield and quality.

E-mail: Richard.Reich@ncagr.gov
1001 Mail Service Center, Raleigh, North Carolina 27699-1001 (919) 707-3015 Fax (919) 733-1141
An Equal Opportunity Employer

Successful organic tobacco production includes management tools such as O-Tac. For the above reasons, we support the approval of natural fatty alcohol sucker control products in organic tobacco production. They are critical to sustaining and continuing to grow not only North Carolina's organic tobacco acreage, but also the acreage and production of other organic crops. Please feel free to contact us if you have any questions.

Sincerely,

Richard C. Reich

Richard C. Reich, Ph.D.
Assistant Commissioner

cc: Commissioner Steven W. Troxler

USDA

United States Department of Agriculture

Office of the Secretary
Washington, D.C. 20250

FEB 8 2018

RECEIVED
FEB 14 2018
NCDA&CS
Assistant Commissioner

Richard C. Reich, Ph.D.
Assistant Commissioner
North Carolina Department of
Agriculture and Consumer Services
1001 Mail Service Center
Raleigh, North Carolina 27699

Dear Dr. Reich:

Thank you for your letter of January 16, 2018, regarding organic tobacco production in North Carolina. In your letter, you expressed support for the allowance of synthetic fatty alcohols in organic tobacco production for sucker control.

The U.S. Department of Agriculture (USDA) organic regulations only allow synthetic substances that appear on the USDA National List of Allowed and Prohibited Substances in organic crop and livestock production (National List). Synthetic fatty alcohols are not currently included on that list and are not currently allowed for organic production.

Adding a synthetic substance to the National List requires a recommendation from the National Organic Standards Board (NOSB or Board). At this time, USDA has not received a recommendation from NOSB to add synthetic fatty alcohols. USDA did previously receive a petition to allow fatty alcohols in organic production. However, at NOSB's most recent meeting, the Board unanimously voted to not support the addition of fatty alcohols to the National List. The Board's decision was based on its review of the petition against the criteria detailed in the Organic Foods Production Act. The Board could revisit this topic if they receive a new petition that includes new information.

Again, thank you for your letter and your support of organic agriculture.

Sincerely,

Sonny Perdue

Sonny Perdue
Secretary

carolina farm
stewardship association

July 12, 2018

Dr. Paul Lewis
Director, Standards Division
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2642-South, Stop 0268
Washington, D.C. 20250-0268

Dear Dr. Lewis:

The Carolina Farm Stewardship Association (CFSA) is a member-based 501(c)(3) organization representing 3,000 farmers, businesses and consumers in North and South Carolina, with a mission to build, advocate for, and educate about the systems to support a regional food system centered on organic agriculture. Founded in 1979, CFSA is the oldest sustainable agriculture organization in the Southeast.

It has come to our attention that Green Ag Supply, LLC has re-filed its petition to add fatty alcohols to the National List, specifically for use in controlling the growth of suckers on organic tobacco plants.

We urge the NOP to send Green Ag Supply's petition to the National Organic Standards Board (NOSB) for review. Many organic farmers in the Carolinas rely on fatty alcohols to produce their tobacco crops—and their tobacco crops form an integral part of diversified cropping systems and business plans. Certified organic tobacco production represents a large segment of the 156-million-dollar organic industry in the Carolinas. Without the availability of fatty alcohols, farmers will face an insurmountable barrier to bringing their crops to market.

CFSA is not alone in this request. Attached to this letter you will find the names of certified organic tobacco farmers who join us in asking for the opportunity to provide the NOSB with comments and data to support our position: that fatty alcohols are essential to Organic tobacco production, and that their use is compatible with the principles of Organic agriculture.

When the NOSB considered the petitioner's request at its meeting in November 2017, it did not hear comments from tobacco farmers. Although this regrettable fact does not require the NOSB to review the petition again, it does raise serious concerns about whether the NOSB made a fully-informed decision.

If the NOP sends the new petition to the NOSB for review, we are confident that a significant number of organic tobacco farmers will submit comments that provide the Board members with important information which they lacked in 2017—in particular, information about the lack of effective alternatives to fatty alcohols and the importance of organic tobacco as a crop for their farms and families.

Thank you for your consideration, and for all your work on behalf of organic agriculture.

Sincerely,

Roland McReynolds
Executive Director
Carolina Farm Stewardship Association

RM/gk

Enclosure

cc: Dr. Jennifer Tucker, Deputy Administrator, NOP
Ray Starling, USDA Chief of Staff

The undersigned farmers join the Carolina Farm Stewardship Association in requesting that the National Organic Program send the petition to add fatty alcohols to the National List of allowed substances to the National Organic Standards Board for review:

Billy Carter
Carter Farms
Moore County, NC

Jennifer Daniels
Windy Creek Farms
Sampson County, NC

J.G. Clayton
Clayton Farms
Vance County, NC

Kent Fann
Robert Fann
Fann Family Farms
Sampson County, NC

David Hight, Jr.
Hight Family Farms
Warren County, NC

Joseph Warren, Jr.
Joseph Warren III
Little Man Farming, Inc.
Sampson County, NC

Philip Smith
Philip Smith Farm
Franklin County, NC

Ricky Lasley
Lasley Family Farm
Rockingham County, NC

George Myers
Myers Brothers Farm
Caswell County, NC

Ashley White
White Ridge Farm
Warren County, NC

David Rose
Allen Rose
Charles Rose
J.B. Rose and Sons, Inc.
Nash County, NC

Daniel Byerly
Daniel and Danny Byerly Farm
Forsyth County, NC

Mark Wheeler
Wheeler Farms
Rockingham County, NC

Grover Douglas
Douglas Farms
Lee County, NC

Clay Strickland
Sherrill Strickland
Strickland Organics, LLC
Sampson County, NC

James Blalock
Blalock Tobacco Farms
Orange County, NC

Jeff Preddy
Preddy Farms, LLC
Granville County, NC

Tim Yarbrough
Yarbrough Farms
Caswell County, NC

Edward Lunsford
Lunsford Farm
Caswell County, NC

William Durant
William Durant Farm
Horry County, SC

Johnny Brown
Matt Brown
Brown Farms
Guilford County, NC

Randy Harris
Harris Farm
Vance County, NC

Roger Tate
Tate, Inc.
Orange County, NC

Michael Hocutt
Hocutt Farms, Inc.
Johnston County, NC

Ryan Lambeth
R.W. Lambeth Farms
Guilford County, NC

Samuel Johnson
Neal Johnson Organics
Johnston County, NC

Matthew Brown
Matt Brown Farms
Horry County, SC

David Hight
A&H Organic Farm, Inc.
Warren County, NC

ITEM B.14 References

Commerical Confidential Information Statement:

We are not declaring any *Confidental Business Information (CBI),* at this time!