

Date: April 18, 2003

To:

National Organic Standards Board, c/o Robert Pooler, Agricultural Marketing Specialist, USDA/AMS/TM/NOP, Room 2510-So., Ag Stop 0268, P.O. Box 96456, Washington, D.C. 20090-6456. Phone: 202/720-3252. Fax: 202/205-7808. e-mail: nlpetition@usda.gov

Dear Mr. Pooler.

The enclosed petition for Glycerine Oleate is being submitted by the following company.

California Certified Organic Farmers
1115 Mission St.
Santa Cruz, CA 95060
(831) 423-3362
www.ccof.org
(prepared by Zea Sonnabend)

**Petition for Amending the National List of the USDA's
National Organic Program**

Glycerine Oleate (Antifoam)

Petitioners are required to provide the following information as applicable:

Category for inclusion on or removal from the National List:

- Synthetic substances allowed in Crops

Common name

Glyceryl oleate; Glycerol oleate; 1-Oleoyl-sn-glycerol; 9-Octadecenoic acid (9Z)-, ester with 1,2,3-propanetriol (9CI); PEG-15 Tallow polyamine; Polyethylene glycol (15) tallow polyamine

Manufacturers name, address and telephone number

Protex International (one of several)
6 Rue Barbes
82305 Levallois, Paris, France
Tel: 33 (0) 1 41 34 14 00
<http://www.protex-international.com/>

List of uses, rates and applications for crops and livestock uses, mode of action for handling uses

Used as an antifoaming agent in micronized wettable sulfur. This enables the product to be mixed in a tank effectively and sprayed on evenly. A label for a formulated product containing this inert is attached (see doc #1). The label shows rates of application of the formulated product of which all the inerts consist of 20%. The Cerexagri company has

disclosed the fact that the glycerine oleate is listed at 0.05% by weight of the formulated product.

Sources and detailed description of manufacturing procedures:

- See TAP review for glycerol monooleate (see doc #2) for general information on manufacturing. Of the several ways to make this compound, it is unknown which is used for this brand of inert. Information strongly points to it being derived from vegetable oils rather than petroleum however. Note that the compound in the TAP review is referred to by three different CAS numbers and this petition refers to one of these: CAS #37220-82-9. Therefore much of the information in the previous TAP review is relevant to this petition. Please see section below for a discussion of the CAS numbers.

Summary of any previous reviews by state or private certification agencies:

- Reviews are unknown to the petitioner, but prior to implementation of the National Organic Program Rule on October 21, 2002, most US certifiers allowed the formulated micronized sulfur products containing this inert. Known to this petitioner were acceptance by CA Certified Organic Farmers, Oregon Tilth, and the WA State Department of Agriculture.

Regulatory status with EPA, FDA or state authorities

- This particular CAS number is not listed as GRAS or anywhere on the FDA website. It therefore is not used in food.
- This CAS number appears on EPA List 3 of inert ingredients which have not completed review.
- It is used in many cosmetic products but it is unknown which exact CAS number the common name refers to.

Chemical Abstract Service (CAS) number or other product #, samples of labels:

- CAS # 37220-82-9 for glycerine oleate. A similar CAS number of 25496-72-4 is commonly referred to as glycerol monooleate and technically as "9-Octadecenoic acid (9Z)-, monoester with 1,2,3-propanetriol (9CI)". This was the main CAS number of the substance that has already been reviewed by the Technical Advisory Panel of the NOSB. The difference appears to be that CAS # 25496-72-4 refers only to the monoester form of the substance, while the CAS # 37220-82-9 is more general and includes two esters: mono-oleate and di-oleate. (this information is from confidential email from the EPA and has been confirmed through personal communication with the Cerexagri company who makes the formulated product). The difference between the two esters is primarily in their water solubility.
- Other numbers: # EINECS 253-407-2. Other Registry numbers (from PAN database): # 149370-77-4, # 37310-82-0, # 37348-67-7, # 42610-89-9, # 51202-39-2, # 8052-34-4
- (see doc. #3) Technical Data Sheet from Lambent Technologies product with the same CAS number

Physical properties of the substance and chemical mode of action: including environmental impacts, interactions with other materials, toxicity and persistence, effects on human health, effects on soil organisms, crops or livestock

- (see doc. #2) TAP review for Glycerol monooleate contains the full description of

physical properties, mode of action, interactions with other materials, toxicity and persistence and effects on human health. Note that this CAS number (# 37220-82-9) has a different molecular formula than what is presented in the TAP review: C18-H34-O2.x-C3-H8-O3.

- (see doc. #4) This research article contains a good description of how foam is formed and then broken up with defoamers – the mode of action.
- (see doc. #5) A .gif chart with a clear explanation of how esterification is done for both oils and petroleum derivatives.
- From the same source as the chart comes much information on how glycerol oleate is used in cosmetics with “outstanding care effects, such as enhancing of the skin lipid layer.” Some of the body care products that contain glycerol oleate include: Weleda cosmetics (many products), Peelu natural toothpaste, Preparation H cream, Labello lip balm. The toothpaste and the lip balm are likely to enter the human digestive system. The effect on human health from a 0.05% portion of a sprayed sulfur on fruit trees used at least two months before harvest is not likely to be greater than that.

Safety information, including a MSDS (Material Safety Data Sheet) and report from National Institute of Environmental Health Studies (NIEHS):

- (see doc. #6) MSDS for formulated product: Microthiol Disperss.
- (see doc. #7) Pesticide Action Network (PAN) Pesticide Database sheet, with much toxicity information. This web link is:
http://www.pesticideinfo.org/Detail_Chemical.jsp?Rec_Id=PC42
- NIEHS – no results

Research information, including research reviews and bibliographies:

see the bibliography from the TAP review done for glycerol monooleate (attached appendix #2).

California Certified Organic Farmers (CCOF) 2000. Certification Handbook. CCOF, Santa Cruz.

Cerexagri, Inc., label for Microthiol Disperss. Appended Document #1.

Cerexagri, Inc., Materials Safety Data Sheet for Microthiol Disperss. Appended Document #6.

Chemfinder. 2001. Glycerol oleate. <http://chemfinder.cambridgesoft.com/result.asp>

Christiano, Steven & Kenneth Fey, 2002, Silicone antifoam performance enhancement by nonionic surfactants in potato medium. *J. Ind Microbiol Biotechnol* (2003) 30: 13-21.
Appended Document #4

Denevan, Bill, Happy Valley Farm and CF Fresh, 2003, Letter concerning need for micronized sulfur. Appended Document #9.

Formella, Tim, Manager of Product Registrations, Cerexagri Inc.. 4/18/03, email correspondence.

Formella, Tim, Manager of Product Registrations, Cerexagri Inc.. 4/17/03, letter concerning Microthiol Disperss. Appended Document #8.

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Hill, Karlheinz, 2001, New cosmetic raw materials from fats and oils, Guest article on Skin Care Forum website, http://www.scf-online.com/english/26_e/rawmaterials26_e_.htm
Figure 1 (gif) about production of surfactants. Appended Document #5

Lambert Technology, Technical Data Sheet for Lumulse Glycerol Monoleate. Appended Doc. #3

Leifer, Kerry, EPA Registration Division, 4/7/03 email correspondence to Kim Burton, NOSB

Lip Balm Users Anonymous, <http://www.kevdo.com/lipbalm/recovery.html>. accessed 4/14/03

Organic Materials Review Institute, September, 2001, TAP review of Glycerol Monoleate (processing). Appended Document #2.

Pesticide Action Network of North America, Pesticides Database: Oleic Acid, glycerol ester entry, http://www.pesticideinfo.org/Detail_Chemical.jsp?Rec_Id=PC42 Accessed 4/16/03.
Appended Document #7.

Petition justification statement - why the synthetic substance is necessary, alternatives that could be used, beneficial effects to the environment, etc:

Organic apple and pear growers use micronized sulfur to control scab and mildew. Organic grape growers also use it, especially raisin and table grape producers, for mildew. CCOF has 82 Certified Organic apple growers, representing more than 1000 acres. Almost all of them are in areas susceptible to scab and mildew which is encouraged by rainy and humid conditions. There is considerably more apple acreage in Washington and Oregon, and most of those growers have scab as well. The micronized forms of sulfur are smaller particles than regular wettable sulfur and will go into and stay in solution better, resulting in better coverage of trees and better efficacy. The micronized form of sulfur is used only in the winter and spring months. Use is discontinued usually by May 15th and always by June; this creates a period of at least 6 weeks before harvest for pears and two months or more for apples.

There are three brands of micronized sulfur commonly available on the west coast: Thiolut, Kumulus, and Microthiol. Thiolut was removed from the approved Brand Names Product Lists of both Organic Materials Review Institute (OMRI) and the Washington State Department of Agriculture (WSDA) in 1999 or so when it was determined that the (disclosed) List 3 inert ingredient in it would not easily be able to be reviewed with enough confidence to determine that it was appropriate for organic use. Kumulus has only List 4 inert ingredients and therefore has been allowed by some certifiers, but because it has no defoamer in it, it is very difficult to use and does not seem to be working very well.

The third brand, Microthiol, has the inert in it which this petition supports. It is the opinion of the petitioner that this inert ingredient is safe enough that it at least merits consideration for being added to the National List. If this inert is approved, we expect to see other companies reformulate or make new products with it to meet the needs of organic growers.

Three alternatives to glycerine oleate are discussed below. One is an alternative antifoaming agent, while the other two are alternatives to using an antifoaming agent. They are: 1. Kumulus brand micronized sulfur, 2. Wettable (non-micronized) sulfur, and 3. Vegetable Oil as an antifoaming agent.

The brand of sulfur without an antifoam agent, Kumulus, results in splotchy looking trees and a large use of sulfur. Although there is some availability of the product at the beginning of the season, the supply will run short as growers feel they are forced to use it and buy the existing stocks. Growers with smaller trees will have more success with it because it will not be as hard to achieve coverage on a small tree.

Non-micronized sulfur must be used very frequently to get any results, and even then the results are less than optimal. While sulfur is approved for organic production, it is not something that any grower wants to apply in excess, because although soils and plants need some sulfur, many soils already have a sufficient amount and excess causes problems. Among these problems are a change in pH downwards and negative effects on soil microorganisms. These negative effects are more significant from a large quantity of sulfur applied, and no doubt outweigh any negative soil effects of a 0.05% amount of glycerine oleate.

It most likely would be possible to re-formulate the product or create a new product using a non-

synthetic vegetable oil defoamer, or another glycerol-based compound that is on EPA List 4. However, this particular company has declined to do so (see document #) and any company that did do so faces a one to two year process of getting registered by the EPA after they have invested time in developing a formulation that works.

The NOSB has recognized in their public meetings that the policy passed to prohibit all List 3 inert ingredients has some flaws. While it is an admirable long-term goal, it is causing much disruption for long-time organic growers for a few specific types of organic materials. We are making strong progress in getting products re-formulated, finding out which products are acceptable, and working with companies and the EPA to meet the needs of organic growers. We have narrowed down the problematic issues, but this is one of the big ones for fruit growers. Approving this substance is one of the positive steps the NOSB can take to address list 3 inerts that are necessary in organic production in current circumstances and yet have a minimal impact on human health or the environment.

- (see doc. #8) Letter from Cerexagri Corp. confirming that they do not intend to reformulate.
- (see doc. #9) Letter from a grower, Bill Denevan, explaining his need for micronized sulfur.

Commercial Confidential Information Statement - describing information that is considered to be confidential business or commercial information:

- The company who makes the formulated micronized sulfur product which contains this inert ingredient has been very cooperative and has disclosed information for this petition. Therefore there is no Confidential Business Information here.