

Petitions should be submitted in duplicate to:
National Organic Standards Board,
c/o Robert Pooler, Agricultural Marketing Specialist,
USDA/AMS/TM/NOP, Room 2510-So., Ag Stop 0268,
PO Box 96456,
Washington, DC 20090-6456.
Phone: (202) 720-3252.
Fax: (202) 205-7808.
E-mail: nlpetition@usda.gov.

From:
Kelly Shea
Horizon Organic Dairy
6311 Horizon Lane
Longmont, CO 80503
Phone: (303) 530-2711
Fax: (303) 527-3392
E-mail: kellys@horizonorganic.com
<http://www.horizonorganic.com>

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

HYDROXYQUINOLINE SULFATE

Category for inclusion on the National List:

205.603.b

As a synthetic, allowed ingredient, in a topical herd health item

Other Names:

Hydroxyquinoline Sulfate

8-Hydroxyl Quinoline Sulfate U.S.P. (United States Pharmacopoeia)

Synonyms:

8-Quinolinol, Sulfate (2:1) (Salt)

Chinosol

Cryptonol

Happy

Octofen

Oxine Sulfate

Oxyquinoline Sulfate

8-Quinolinol, Hydrogen Sulfate (2:1)

8-Quinolinol Sulfate

Sunoxol

Superol

8-Hydroxyquinoline Sulfuric Acid Salt

Quinosol

CAS Number: 134-31-6

Base Chemical Name: Hydroxyquinolinesulfate, 8-

Primary Name: 8-Hydroxyquinoline Sulfate

Chemical Formula: C₁₈H₁₄N₂O₂.H₂O₄s

8-hydroxyquinoline sulfate - Was used as component of cottage cheese. It has been recently banned as a coagulant in food products.

Carcinogenicity: Not listed by ACGIH, IARC, NIOSH, NTP, or OSHA.

Composition:

--Theoretical 8-hydroxy-quinoline content: 71.42%

--Sulfuric acid: 24.15%

--Water: 4.43%

The salve is then 0.3% of the above composition of hydroxyquinoline sulfate in a base of petroleum and lanolin.

Properties:

Molecular Weight: 406.05

Yellow microcrystalline powder with a faint smell of saffron, slightly hygroscopic

Highly soluble in water, even cold

Very sparingly soluble in alcohol or other organic solvents

The 2% aqueous solution has a pH of 3.2

Applications:

Human Medicine:

External use:

--A powerful non-toxic, non-caustic antiseptic

Internal use:

--Prevention and treatment of gynecological infections, (metritis, vaginitis), restores the vaginal acid balance.

--Treatment of infections in the urinary tract

--Treatment of diarrhea and colitis without harming the intestinal flora

--Disinfectant used in oto-rhino-laryngology

--Many other documented uses

Serology:

--Stabilizing agent for serum and vaccines

Veterinary Medicine:

--Used in the composition of many products for the treatment of poultry diseases

--Fungicide which is harmless to intestinal flora

--An antiseptic widely used in artificial insemination techniques

--Disinfection of stables contaminated with brucellosis

Cosmetic:

--Antiseptic used in ointments and creams used for skin treatment and in certain hair lotions

--Anti-perspirant (deodorant)

--Agent for stabilizing oxygenated water solutions

Specific Use: Ingredient in Bag Balm Antiseptic Salve

Manufacturer's Name, address, and telephone number

Bag Balm:

Dairy Association Co., Inc.

Lyndonville, VT 05851

802-626-3610

Hydroxyquinoline Sulfate:

Napp Technologies

299 Market Street

Saddle Brook, NJ 07663

201-843-4664

List of uses, rates, and applications also mode of action for handling uses:

This synthetic is used in personal care, pharmaceutical and food processing. The product we use, Bag Balm, has 0.3% Hydroxyquinoline Sulfate in a petroleum-lanolin base. It is primarily designed to treat cows' udders that have been cut, scraped, chapped, or sunburned. It is used for cows' udders that have become caked or congested due to calving, or bruising, and is also put on teats to prevent freezing.

It is not to be applied on deep skin wounds or punctures; it is not meant for internal use. There are no known side effects or reactions with other medicines.

Regulatory status with, FDA, or state authorities

Bag Balm is registered with the FDA for use on animals only. However, hydroxyquinoline sulfate is controlled in cosmetics and toiletries, has been used for preserving syrups, and as an antioxidant synergist.

Status among US certifiers: This type of topical salve has been allowed by US certifiers. It contains no antibiotics, no GMOs, and no hormones.

OMRI:

The petroleum portion is restricted, not prohibited

MSDS:

See attached

Petition justification statement:

Hydroxyquinoline sulfate is the active ingredient in a salve primarily used to treat cow's udders that have been cut, scraped, chapped or wind burned. The salve soothes the skin by absorbing water on the area you have applied the salve. The hydroxyquinoline sulfate works as an anti-bacterial to inhibit bacterial growth, so skin irritation will decrease. There are no known side effects or reactions with other medicines. When it is working, you notice that the udder softens and milk flows freely. You notice a softening of the skin and a decrease in symptoms such as redness and swelling.

References:

Bag Balm Pamphlet, Dairy Association Co., PO Box 145
Lyndonville, VT 05851

Material Safety Data Sheet, on file with the US Department of Labor, Occupational Safety and Health Administration, provided by Dairy Association Co., Inc. Lyndonville, VT 05851

Taber's Cyclopedic Medical Dictionary, F.A. Davis Company, Philadelphia, p. 1436, 1655, 791.

Physician's Drug Handbook, Springhouse Corporation, Springhouse, Pennsylvania, p. 1076-1081


Material Safety Data Sheet, on file with the US Department of Labor, Occupational Safety and Health Administration, provided by Napp Technologies, Inc. Saddle Brook, NJ

Hydroxyquinoline Sulfate Technical Documentation, provided by Napp Technologies, Inc. Saddle Brook, NJ

MATERIAL SAFETY DATA SHEET

Common name : * 8-HYDROXY QUINOLINE SULPHATE

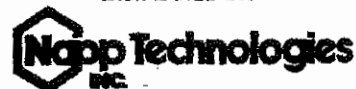
Date : 24/02/99

1 IDENTIFICATION	
- Supplier	: ORGACHIM 3 rue Octave Fauquet - BP n° 7 76350 OISSEL
- Emergency phone number	: Tel. 33.2.35.64.50.50 Fax 33.2.35.64.50.30 Tel. accident transport : 33.2.35.64.50.50 Centre antipoison Paris : 33.1.40.37.04.04 200 rue du Faubourg St Denis
	DISTRIBUTED BY:  299 MARKET STREET, SADDLE BROOK, NJ 07663 TEL: (201) 843-4664 FAX: (201) 843-4737
2 COMPOSITION – INFORMATION ON INGREDIENT	
- Substance	: 8-HYDROXY QUINOLEINE SULPHATE > 98 % W/W
- N° CAS	: 134-31-6
- Risk	: Harmful if swallowed
3 IDENTIFICATION ON THE PREPARATION HAZARDS	
- Classification	: Xn
- Risk	: Harmful if swallowed
4 FIRST AID MEASURES	
- General instructions	: Remove the affected person from the danger zone to a well-ventilated place and protect from under cooling never give anything by mouth to an unconscious person and don't induce vomiting. Call antipoisonous center.
- Inhalation	: Refer general instructions paragraph.
- Ingestion	: If swallowed, seek medical advice immediately and show the container or label. Note to the physician : no specific antidote is known, apply symptomatic therapy.
- Contact with eyes	: Rinse with plenty of clean water.
- Skin contact	: Take off all contaminated clothing and thoroughly wash the affected parts of the body with soap and water.
5 FIRE-FIGHTING MEASURES	
- Recommended extinguishing means	: Not inflammable. Protect from heat by mean of waterspray.
- Extinguishing means to avoid	: Direct jet of water.
- Unusual risks	: Products of decomposition by pyrolyses : carbon et nitrogen oxides and iodine.
- Unusual safety devices	: In case of pyrolysis risk (heat from fire of others flammable products), wear autonomous respiratory equipment. Restrain extinguishing water, neutralize or chminate it in authorised facilities.
6 ACCIDENTAL LEAKAGE	
- Personal protective equipment	: Wear suitable protective clothing and gloves. Gloves : cotton or natural latex

7 HANDLING AND STORAGE	
- Handling	: When using do not eat, drink or smoke, wear suitable protective clothing and gloves.
- Storage	: Keep out of reach children, away from food, drink and animals feeding stuffs. Keep container tightly closed and store in a dry place.
8 EXPOSURE CONTROL	
- Disposals in general	: } cf. n° 6 and 7
- Individual means of protection	: }
- Respiratory protection	: Protection against dust
- Hands protection	: }
- Eyes protection	: } Wear suitable protective clothes, gloves and eye/face protection
- Skin protection	: }
9 PHYSICO CHEMICAL DATA	
- Appearance	: Yellow cristalline powder
- Odour	: Odourless.
- Melting point	: 188-189°C
- Solubility	: Very lightly soluble in ethanol and organic solvents
- Hydrosolubility	: Very soluble.
- Density	: 0,3 - 0,5
10 STABILITY / REACTIVITY	
- Circumstances to avoid	: Heat and humidity
- Materials to avoid	: Metallic container
- Hazardous products of degradation	: cf. n° 5
11 TOXICOLOGICAL DATA	
- LD50 oral/rat mg/kg	: Male 1490 - Femelle 1250.
- LD 50 intravenous/rat mg/kg	: > 4000
- LC 50 inhalation/rat/mg/kg	: > 4200
- LC 50 bluegill sunfish	: No determined.
- Skin irritation (rabbit)	: No irritating.
- Eye irritation (rabbit)	: Very Lightly irritating.
12 ECOLOGICAL DATA	
- Bees toxicity	: }
- Birds	: } Practically not toxic
- Aquatic faun	: }
- CE 50 (3 h) mg/l	: > 0,5
- Rainbow trout LC 50 (96 h) mg/l	: > 10
- Bluegill sunfish LC 50	: not determined
13 DISPOSAL	
- Product	: Eliminate in authorized facilities
- Packing	: Reuse forbidden, empty carefully
- Residue products of cleaning	: Reuse forbidden, empty carefully

14 TRANSPORT	RTMDR	IMDG	DATA
- Class - Number or page - Sticker - U.N number - Marine polluting	: Not classified : Not classified : Not classified : Not classified :	Not classified Not classified Not classified Not classified	
15 REGULATION INFORMATION			
- Xn - Risk	: Nocif : R 22 S 1/2 S 20/21	Harmful if swallowed. Keep locked up and out of reach of children. When using do not eat, drink or smoke.	
16 DATE VALIDITY			
- This sheet completes the technical sheet of use but it does not replace it. The information contained in this sheet is based on our knowledge of the product at the date of 02/99. Moreover the attention of the users is drawn on the risk possibility taken when product is used for other uses than those for which it is intended to.			

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Technical Documentation

No. 75-020

NEUTRAL 8-HYDROXY QUINOLINE SULFATE

COMMON AND FOREIGN NAMES :

Sulfate Neutre d'Oxyquinoléine

Sulfate d'Oxyquinoléine

Oxyquinoléine sulfate

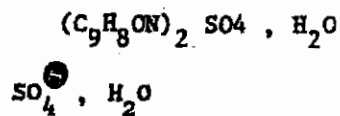
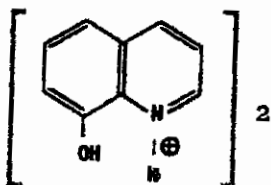
8-Quinolinol sulfate

O-ine sulfate

8-hydroxy quinoline sulfuric acid salt

Oxychinolinum sulphuricum

PHYSICAL PROPERTIES :



Molecular weight 406.05

- Yellow microcrystalline powder with a faint smell of saffron, slightly hygroscopic.
- Highly soluble in water, even cold.
- Very sparingly soluble in alcohol or other organic solvents
- The 2% aqueous solution has a pH of 3.2

COMPOSITION :

- Theoretical 8-hydroxy-quinoline content : 71.42%
- Sulphuric acid : 24.15%
- Water : 4.43%

SPECIFICATIONS :

Requirements of the pharmacopaeias		Our standards
8-hydroxy-quinoline %)	95% purity) (expressed in terms) of anhydrous sulphate)	71.4 ± 0.5
Sulphuric acid %)	(Pharm. Helv. V)	24.15 ± 0.25
Melting point	178 - 185°C (Danica 1948 II)	188 - 189°C (Instantaneous melting point obtained with a Maquenne block)

The melting points stated in some pharmacopaeias may differ according to the techniques employed.

The relatively precise standards which we show here are the result of averages arrived at over a vast number of batches and are intended to give our customers a clear picture of the physico-chemical properties of our products, since our guarantee extends only to our deliveries conforming to current pharmacopaeias.

Particle size :

50 to 63 microns	33%
63 to 80 microns	28%
80 to 100 microns	15%
100 to 125 microns	11%
Larger than 125 microns	33%

IDENTIFICATION :

- The addition of a few drops of a dilute ferric chloride solution to an aqueous solution of neutral 8-hydroxy-quinoline sulfate produces an emerald green colouring.
- The addition of alkali to an aqueous solution of neutral 8-hydroxy-quinoline sulfate causes precipitation of 8-hydroxy-quinoline which redissolves in an excess of alkali.

ANALYSIS :

Quantitative analysis of 8-hydroxy-quinoline

The bromination method described in "Technical Documentation" on 8-hydroxy-quinoline, is used in conjunction with 1 g of sample.

The 8-hydroxy-quinoline sulfate content should be at least :



This corresponds to a minimum 8-hydroxy-quinoline content of 71%.

Quantitative analysis of Sulfuric acid

Method 1

Sample 1.2 g. Dissolve this in 300 ml of water ; add 1 ml concentrated hydrochloric acid, then bring close to boiling point. Precipitate the sulfate with 40 ml of a boiling 5% solution of $\text{BaCl}_2 \cdot 2\text{H}_2\text{O}$.

After leaving for two hours in a bain marie at 80°C, filter slowly over an ashless filter, wash with boiling water until all the chloride ions disappear, and calcine at 900°C.

Calculation :

Let p be the weight of the sample in g.

m be the weight of barium sulfate obtained

$$\% \text{H}_2\text{SO}_4 = \frac{m \times 42.017}{p}$$

Method 2

Principle :

The method is based on the fact that 8-hydroxy-quinoline sulfate is the salt of a strong acid and a weak base ($\text{p}K_1 = 5.09$; $\text{p}K_2 = 9.82$), measurable with sodium hydroxide. In an alcohol medium, accuracy is improved and precipitation of 8-hydroxy-quinoline avoided. Bromothymol blue is used as the colour indicator.

Reagents : Methanol or ethanol, distilled

Bromothymol blue, 0.1% in 20% alcohol

0.1 N sodium hydroxide.

Method :

Dissolve an accurately weighed amount of about 0.8 g sample in 65 ml methanol in a 250 ml Erlenmeyer flask. Add 15 drops bromothymol blue and titrate with sodium hydroxide until the green tint appears.

Let p be the weight of the sample in g.

n be the number of ml of sodium hydroxide solution used

t the titre of the sodium hydroxide solution

$$\% \text{H}_2\text{SO}_4 = \frac{98.05 \times n \times t \times 100}{2 \times 1000 \times p} = \frac{4.9025 \text{ nt}}{p}$$

Ref.: LACROIX : *Analytica Chimica Acta* - Vol. I (1947) - page 263.

Sulfuric ash : Taking the usual precautions, calcine 2 g of the sample, previously moistened with a few drops of concentrated sulfuric acid, at 700°C.

The residue by weight ought not to represent more than 0.3% of the weight used.

Quantitative analysis with water : The Karl-Fischer or the azeotropic distillation method should be used.

APPLICATIONS :

Human medicine :

External use

- A powerful non-toxic, non-caustic antiseptic used for impregnating the gauze of certain dressings.

Internal use

- Prevention and treatment of gynaecological infections (metritis, vaginitis), restoring the vaginal acid balance.
- Treatment of infections of the urinary tract (pyelitis, cystitis, colibacillosis).
- Treatment of diarrhea and colitis without harming intestinal flora.
- Disinfectant used in oto-rhino-laryngology.
- Anthelmintic, active in all media (neutral, acid or basic).
- Compatible with sulphonamides and antibiotics
- Does not coagulate albumins.

Serology

- Stabilising agent for sera and vaccines (inhibits microbial flora).

Veterinary medicine

- Used in the composition of many products for the treatment of poultry diseases, particularly coccidiosis in birds.

- Fungicide which is harmless to intestinal flora
- An antiseptic widely used in artificial insemination techniques.
- Available as vaginal rods or pellets.
- Disinfection of stables contaminated with brucellosis, by spraying a 1:1000 (approx.) solution over the stable litter and walls.

Cosmetic

- Antiseptic used in ointments and creams used for skin treatment and in certain hair lotions.
- Agent for stabilising oxygenated water solutions, at the rate of 0.1 to 0.5 %.
- Anti-perspirant (deodorant).

Industry

- Preserving agent for mechanical paper pulps :
Spraying of a dilute solution of 70 to 120 g 8-hydroxy-quinoline sulfate per metric ton of pulp in 50% humidity ensures excellent protection against mildew attack.
- Protection of packaging cartons by spraying at the rate of 0.5 to 1 g per sq.m.
- Subject to chemical compatibility, may be incorporated in paints, so imparting permanent fungistatic properties to them.

MARKETED AS :

Fine crystalline powder.

STORAGE :

In the original packaging.

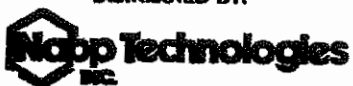
PACKAGING :

- 1) For small quantities of 1 to 9 kg
2 types of packaging, 1 and 5 kg, in the form of a cardboard box with iron hoops, lined on the inside with a plastic bag.
- 2) For quantities of 10 kg and more
2 types of packaging, 10 and 50 kg, in the form of a cardboard drum, with iron hoop, lined on the inside with a plastic bag.

All our forms of packaging are approved for transport by land, air and sea.

The sole object of the details given in this pamphlet is to provide our customers with useful information of the product and its possible application, but under no circumstances may they be regarded as binding.

Our Technical Department is at your disposal for any further information you may require.



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299 MARKET STREET SADDLE BROOK, NJ 07663
TEL: (201) 843-4664 FAX: (201) 843-4737

Oissel, April 6th, 1998

Subject : 8-Hydroxyquinoline sulfate

We certify that 8-hydroxyquinoline sulfate stored under normal conditions of temperature and humidity in its original container retains its original chemical characteristics during 5 years.

M. MARY
Quality Assurance Manager

DISTRIBUTED BY:

Napp Technologies
INC.

209 MARKET STREET, SADDLE BROOK, NJ 07663
TEL: (201) 843-4664 FAX: (201) 843-4737

ORGACHIM

OISSEL, 27 May 1977

SPECIFICATIONS

SULFATE D'HYDROXY-8 QUINOLEINE
8-Hydroxyquinoline sulphate

Appearance	A yellow powder
8-Hydroxyquinoline	50.6 - 52.6 %
H₂SO₄	29.5 - 32.5 %
pH (2% in water)	# 3.2
H₂O	# 4.4 %
Solubility (20% in water)	Good
Assay	> 98.5%
Shelf life	5 years after manufacturing date

Analytical Department Manager



ORGACHIM

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TEL: (201) 843-4664 FAX: (201) 843-4737

July 23th, 1997

To whom it may concern :

We Orgachim at address : 3, rue Octave Fauquet - 76350 Oissel (France) hereby declare that, during the process of :

8-hydroxy quinoline sulfate (CAS 134-31-6)

None of the solvents listed below are used or produced as by products :

- . Benzene
- . Chloroform
- . 1,4 - Dioxan
- . Methylene Chloride
- . Trichloroethylene

ORGACHIM
3, rue Octave-Fauquet Jean FREYRE
B.P. 7 Plant Manager
76350 OISSEL
Tél. : 35 64 50 50





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299 MARKET STREET, SADDLE BROOK, NJ 07663
TEL: (201) 843-4664 FAX: (201) 843-4737

Quality Statement

To Whom It May Concern :

RE : SAFETY OF MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE
REGARDING THE RISK OF TRANSMITTING SPONGIFORM ENCEPHALOPATHIES (SE)
AND SCRAPIE.

PRODUCT : SULFATE NEUTRE
8-HYDROXYQUINOLINE SULFATE

We, the undersigned, have thoroughly examined the source of all the active and inactive ingredients, intermediates, solvents, etc. in the above-mentioned product and hereby declare that the finished product has not been derived from any constituent derived from cattle, sheep or goats in anyway whatsoever.

We hereby further undertake to keep our customers updated with all information regarding the safety of this product regarding the risk of transmitting spongiform encephalopathies (SE) and scrapie.

ORGACHIM
3, rue Octave-Fauquet
B.P. 7
76350 OISSEL
Tél. : 35 64 50 50

Jean FREYRE
Plant Manager

Oissel, July 18, 1997

ORGACHIM

ORGACHIM

DISTRIBUTED BY:

Napp Technologies
INC.

299 MARKET STREET, SADDLE BROOK, NJ 07663
TEL: (201) 843-4664 FAX: (201) 843-4737

Oissel, July 11, 1997

To whom it may concern :

- We ORGACHIM at adress : 3, rue Octave Fauquet - 76350 OISSEL (FRANCE) hereby declare that the site will be ISO 9002 audited for final certification before end of 1997.
- We are manufacturing bulk pharmaceutical chemicals following the EU cGMP and we have already been audited and approved as supplier by european pharmaceuticals companies.

As of today we have not filed any DMF with FDA, and thus we have not been audited by them.

Assurance Quality Manager
M. MARY

ORGACHIM
3, rue Octave-Fauquet
B.P. 7
76350 OISSEL
Tél. : 35 64 50 50



ORGACHIM

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299 MARKET STREET, SADDLE BROOK, NJ 07663
TEL: (201) 843-4664 FAX: (201) 843-4737



CERTIFICAT

CERTIFICATE

N° QUAL/1998/9019

AFAQ certifie que le système qualité adopté par,
AFAQ certifies that the quality system developed by :

ORGACHIM

pour les activités suivantes,
for the following activities :

FABRICATION ET VENTE DE PRODUITS DE SYNTHÈSE DE CHIMIE FINE.
FABRICATION A FACON DE PRODUITS DE SYNTHÈSE DE CHIMIE FINE ET DE
FORMULATIONS AGROCHIMIQUES.

MANUFACTURING AND SALES OF FINE CHEMICALS, TOLL AND CUSTOM
MANUFACTURING OF FINE CHEMICALS AND AGROCHEMICAL
FORMULATIONS.

exercées sur le(s) site(s) suivant(s),
carried out in the following location(s) :

3, rue Octave Fauquet B.P. 7 F-78350 OISSEL

a été évalué et jugé conforme aux exigences de la norme.
has been assessed and found to conform to the requirements of the standard :

ISO 9002 (1994)

Le présent certificat, délivré dans les conditions fixées par AFAQ, est valable à dater du.
This certificate, delivered under AFAQ rules, is valid to :

1998-02-02

(année-mois-jour)

jusqu'au

2001-02-01

(year-month-day)

LE PRÉSIDENT DU COMITÉ DE CERTIFICATION
THE PRESIDENT OF THE CERTIFICATION COMMITTEE

LE DIRECTEUR GÉNÉRAL D'AFAQ
THE MANAGING DIRECTOR OF AFAQ

LE REPRÉSENTANT DE L'ENTREPRISE
ON BEHALF OF THE FIRM

A. LADURÉE

O. PEYRAT

PH. MANNSCHOTT

*Not responsible neither with respect to AFAQ nor with respect to the client, for any damage or loss of data or information resulting from the use of this certificate. The present certificate is not valid if it is not signed by the President of the Certification Committee, the Managing Director of AFAQ, and the Representative of the Firm.

become alkaline.

Incompatibility and Storage. As for Hydrogen Peroxide Solution (3 per cent) (above). Strong solutions of hydrogen peroxide are more stable than the weaker solutions.

5904-h

Hydrogen Peroxide Solution (30 per cent) (BAN).

Hydrogen Peroxide Solution (100-volume);
Hydrogenii Peroxidum 30 per centum.

Pharmacopoeias. In Arg., Aust., Belg., Br., Egypt., Eur., Fr., Ger., It., Neth., Nord., Pol., Roum., Span., and Swiss, C. specifies 28 to 32%, Hung. 27.5 to 32%, and Jug. 28 to 31%. U.S. specifies Hydrogen Peroxide Concentrate 29 to 32%.

An aqueous solution containing 29 to 31% w/w of H_2O_2 , corresponding to about 100 times its volume of available oxygen. It may contain a suitable stabilising agent. The U.S.P. permits up to 0.05% of a suitable preservative or preservatives. A clear, colourless liquid. It decomposes vigorously in contact with oxidisable organic matter and with certain metals and also if allowed to become alkaline.

Other industrial strengths of hydrogen peroxide solution are manufactured, including 35% w/w, 50% w/w, and 85% w/w.

Incompatibility as for Hydrogen Peroxide Solution (3 per cent). Store in partially-filled containers having a small vent in the closure, at a temperature of 8 to 15°. Protect from light.

Adverse Effects and Precautions

Strong solutions of hydrogen peroxide produce irritating 'burns' on the skin and mucous membranes with a white eschar, but the pain disappears in about an hour. Continued use of hydrogen peroxide as a mouth-wash may cause reversible hypertrophy of the papillae of the tongue.

It is dangerous to inject or instil hydrogen peroxide into closed body cavities from which the released oxygen has no free exit. Colonic lavage with solutions of hydrogen peroxide as weak as 0.75% has been followed by gas embolism and by gangrene of the intestine.

In Great Britain the recommended exposure limits of hydrogen peroxide are 1 ppm (long-term); 3 ppm (short-term).

There are restrictions in a number of countries on the concentration of hydrogen peroxide allowed in cosmetics.

One case of oxygen embolus and another of surgical emphysema following injection of hydrogen peroxide for wound and abscess cleaning illustrating the hazards of irrigation under pressure or into enclosed body cavities.—J. W. Sleight and S. P. K. Lieter, *Br. med. J.*, 1945, 291, 1706.

Uses and Administration

Hydrogen peroxide is used as a disinfectant and deodorant. It owes its action to its ready release of oxygen when applied to tissues, but the effect lasts only as long as the oxygen is being released and is of short duration; in addition the antimicrobial effect of the liberated oxygen is reduced in the presence of organic matter.

Hydrogen peroxide is used to cleanse wounds and ulcers in concentrations of up to 6%. Injection into closed body cavities is dangerous (see above). Adhering and blood-soaked dressings may be released by the application of a solution of hydrogen peroxide.

A 1.5% solution of hydrogen peroxide has been used as a mouth-wash in the treatment of acute stomatitis and as a deodorant gargle. In dentistry, hydrogen peroxide has been used to clean septic sockets and root canals.

Hydrogen peroxide ear-drops have been used for the removal of wax. Such ear-drops were prepared by diluting a 6% solution of hydrogen peroxide with 3 parts of water preferably just before use.

For bleaching hair and delicate fabrics hydrogen

peroxide 6% should be neutralised or rendered faintly alkaline and diluted with an equal volume of water. In some countries cosmetic product regulations limit the concentration of hydrogen peroxide in hair care products to 12%.

Strong solutions (27 per cent and 30 per cent) of hydrogen peroxide are used for the preparation of weaker solutions.

Hydrogen peroxide and other peroxides have many industrial uses as bleaching and oxidising agents.

In a study involving 49 patients with denture-induced stomatitis a peroxide denture cleaner was found to be no more effective than a placebo cleaning regimen in preventing candidal repopulation of denture or mucosa, or in reducing mucosal inflammation.—D. M. Walker et al., *Br. dent. J.*, 1981, 151, 416.

Preparations

Hydrogen Peroxide Ear Drops (A.P.F.)

Proprietary Preparations

Hioxyl (Quinoderm, UK). Cream, hydrogen peroxide (stabilised), 1.5%.

Proprietary Names and Manufacturers

Bristoventil (DAK, Denmark); Caroxin (Ferrosan, Denmark); Genoxide (Ilietox, UK); Hioxyl (Quinoderm, UK); Oxydol (Petri, Denmark); Oxysept System (Allergen, Australia); Peroxyl (Colgate-Hoyt, USA).

19307-g

4-Hydroxyandrostenedione

4-OHA; 4-OHAD. 4-Hydroxyandrost-4-ene-3,17-dione.

$C_{19}H_{26}O_2=302.4$.

4-Hydroxyandrostenedione is an inhibitor of the aromatase (oestrogen synthetase) system and is under investigation for the endocrine therapy of breast cancer.

References: R. C. Coombes et al., *Lancet*, 1984, 2, 1237; M. J. Daly and M. G. Rowlands, *Pharm. J.*, 1986, 2, 694.

12835-x

Hydroxymethylnicotinamide

N-Hydroxymethylnicotinamide; Nicotinylmethylamide. N-Hydroxymethylpyridine-3-carboxamide. $C_7H_9N_2O_2=152.2$.

CAS — 3569-99-1.

Hydroxymethylnicotinamide is a cholagogue and has been used in the treatment of various disorders of the gall-bladder.

Proprietary Names and Manufacturers

Bilamide (Cilag, Ger.; Bracco, Ital.; Cilag, Switz.); Bilamide (Cilag-Chemie, Belg.); Bionide (Labotec-Pharma, Switz.).

1614-g

Hydroxyquinoline Sulphate

Chinosolum; Oxichinolinum Sulfas; Oxine Sulphate; Oxyquinol; Oxyquinoline Sulfate (USAN); Sulfate d'Orthoxyquinoline. Quinolin-8-ol sulphate; 8-Quinololin sulphate. $(C_8H_7NO)_2 \cdot H_2SO_4=388.4$.

CAS — 148-24-3 (hydroxyquinoline); 134-31-6 (sulphate).

Pharmacopoeias. In Belg. and Rus., Fr., Nord., and Swiss specify monohydrate. Also in U.S.N.F.

A yellow powder. M.p. about 185°.

Very soluble in water; slightly soluble in alcohol; freely soluble in methyl alcohol; practically insoluble in acetone and ether. Store in well-closed containers.

Hydroxyquinoline sulphate has properties similar to those of potassium hydroxyquinoline sulphate (see p.1606) and has been used similarly in the topical treatment of skin infections.

It has been used for preserving syrups and has also been used as an antioxidant synergist since it forms complexes with some heavy metals and thus inhibits catalysis of oxidation by them.

The use of hydroxyquinoline sulphate in cosmetics and toiletries is controlled.

Proprietary Names and Manufacturers of Hydroxyquinoline Sulphate or another Salt of Hydroxyquinoline

Chinosol (Chinosol, Denmark); Chinosolfabrik, Ger.; Oxykin (DAK, Denmark); Semasi (Luitpold, Ger.; Luitpold, Switz.); Strobinal (Gospil, Fr.); Superol (Hoth); Superol, S.Afr.; Trimo-San (Millex-Budlong, Canada); Triva Douche Powder (Boyle, USA).

The following names have been used for multi-ingredient preparations containing hydroxyquinoline sulphate or another salt of hydroxyquinoline—Acti-jel (Cilag, Australia); Ortho, Canada; Ortho Pharmaceutical, USA; Benzazeal (Baltan, Canada); Chinosol (Chinosolfabrik, Switz.); Dermacide (Sabex, Canada); Dermoplast (Ayerst, Australia); Ayerst, Canada; Torbet Laboratories, UK; Medicone Derma-HC (Medicone, USA); Quinoderm (Quinoderm, UK); Quinoderm with Hydrocortisone (Quinoderm, UK); Quinoped (Quinoderm, UK); Rectal Medicone-HC (Medicone, USA); Triva Jel (Boyle, USA).

3725-g

Hymecromone (USAN, INN).

Imecromone; LM-94. 7-Hydroxy-4-methylcoumarin.

$C_{10}H_8O_3=176.2$.

CAS — 90-33-5.

Hymecromone is a cholcretic and biliary antispasmodic. Diarrhoea may occasionally occur. It has been given in doses of 400 mg three times daily before meals. It has also been given by slow intravenous injection as an adjunct to diagnostic procedures.

Proprietary Names and Manufacturers

Bicolie (L'Infa, Arg.); Bilecanis (Boehringer Mannheim, Spain); Cantabilin (Formens), Ital.; Cantabiline (Lipha, Belg.; Médicina, Fr.); Choloveron (Dolorgic, Ger.); Cholospasmin (Lipha, Ger.); Cumarate-C (Jpn); Eurogate (Spain); Himecol (Jpn); Medilla (Omega, Arg.).

12837-f

Hypoglycin A

L-2-Amino-3-(2-methylenecyclopropyl)propionic acid.

$C_7H_{11}NO_2=141.2$.

CAS — 156-56-9.

A toxic substance present in the arillus of unripe akee, the fruit of *Blighia sapida* (Sapindaceae).

Hypoglycin A is responsible for Jamaican vomiting sickness, with symptoms of acute and severe vomiting, hypoglycaemia, CNS depression, convulsions, and coma, frequently fatal.

Glycine might be useful in the treatment of poisoning by the unripe fruits of the Jamaican akee [akee].—H. S. A. Sherratt and S. S. Al-Bassam (letter), *Lancet*, 1976, 2, 1243. See also K. Tanaka (letter), *ibid.*, 1977, 1, 370; H. S. A. Sherratt and S. S. Al-Bassam (letter), *ibid.*, 604.

Further references: R. Haeckel, *Chem. Med.*, 1972, 2, 69; K. Tanaka et al., *New Engl. J. Med.*, 1976, 295, 461; R. Bressler, *ibid.*, 500; D. Billington et al., *ibid.*, 1482.

1936-n

Hypophosphorous Acid (USAN).

Acidum Hypophosphorosum; Phosphinic Acid. $H_3PO_2=66.0$.

CAS — 6303-21-5; 14332-09-1.

Pharmacopoeias. In U.S.N.F.

A colourless or slightly yellow odourless liquid, containing 30 to 32% of H_3PO_2 . Store in airtight containers.

Hypophosphorous acid is used as an antioxidant. Hypophosphates were used in tonics: like the glycerophosphates they are not a suitable source of phosphorus.

----- MATERIAL SAFETY DATA SHEET -----

Dairy Association

BAG BALM ANTISEPTIC SALVE

SECTION I

MANUFACTURER'S NAME: DAIRY ASSOCIATION COMPANY, INC.
 LYNDONVILLE, VERMONT 05851
 EMERGENCY TELEPHONE NUMBER: 1-(802) 626-3610
 CHEMICAL NAME AND SYNONYMS:
 TRADE NAME AND SYNONYMS: Bag Balm Antiseptic Salve
 CHEMICAL FAMILY: 0.3% Hydroxyquinoline Sulfate in a
 Petrolatum-Lanolin Base
 FORMULA: *Eastern Chemical Corp.
 Napp Technologies*

SECTION II - HAZARDOUS INGREDIENTS

Paints, Preservatives, and Solvents	%	TLV (Units)
Pigments	N/A	N/A
Catalyst	N/A	N/A
Vehicle	N/A	N/A
Solvents	N/A	N/A
Additives	N/A	N/A
Others	N/A	N/A

Alloys and Metallic Coatings	%	TLV (Units)
Base Metal	N/A	N/A
Alloys	N/A	N/A
Metallic Coatings	N/A	N/A
Filler Metal Plus Coating or Core Flux	N/A	N/A
Others	N/A	N/A

Hazardous Mixtures of Other Liquids, Solids or Gases	%	TLV (Units)
N/A		

SECTION III - PHYSICAL DATA

BOILING POINT (deg F.): -----
 VAPOR PRESSURE (mm Hg.): -----
 VAPOR DENSITY (AIR = 1): -----
 SOLUBILITY IN WATER: None
 SPECIFIC GRAVITY (H₂O = 1): 0.87
 PERCENT VOLATILE BY VOLUME (%): 2.0 - 3.0%
 EVAPORATION RATE (_____ = 1):
 APPEARANCE AND ODOR: Semi-solid cream, lanolin odor

SECTION IV - FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (Method Used): Above 200 deg F (Tag Open Cup)
 FLAMMABLE LIMITS: N/A
 LEL:
 UEL:
 EXTINGUISHING MEDIA: N/A
 SPECIAL FIRE FIGHTING PROCEDURES: N/A
 UNUSUAL FIRE AND EXPLOSION HAZARDS: None

SECTION V - HEALTH HAZARD DATA

THRESHOLD LIMIT VALUE: Skin Irritation (Rabbit): None
 EFFECTS OF OVEREXPOSURE: N/A
 EMERGENCY AND FIRST AID PROCEDURES: N/A

SECTION VI - REACTIVITY DATA

STABILITY: Stable.
 CONDITIONS TO AVOID:
 INCOMPATIBILITY (Materials to Avoid): -----
 HAZARDOUS DECOMPOSITION PRODUCTS: None
 HAZARDOUS POLYMERIZATION: Will Not Occur.
 CONDITIONS TO AVOID:

SECTION VII - SPILL OR LEAK PROCEDURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED:
 N/A
 WASTE DISPOSAL METHOD: Municipal Sanitary Landfill

SECTION VIII - SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION (Specify type): Not required
 VENTILATION:
 LOCAL EXHAUST: Not required
 MECHANICAL (General): Not required
 SPECIAL:
 OTHER:
 PROTECTIVE GLOVES: Not required
 EYE PROTECTION: Not required
 OTHER PROTECTIVE EQUIPMENT:

SECTION IX - SPECIAL PRECAUTIONS

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING: None
 OTHER PRECAUTIONS: None

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COMPAS Code: 19210010

RAC Approved Date: / /

*CA S 134-31-6: VC 826000
 Chemical Abstract Service*

Material Safety Data Sheet

U.S. Department of Labor

Required under USDL Safety and Health Regulations
for Shipyard Employment (29 CFR 1915)

Occupational Safety and Health Administration

OMB No. 1218-0074

August 17, 2000

Section I

Manufacturer's Name
Dairy Association Company, Inc.

Emergency Phone Number
(802) 626-3610

Address (Number, Street, City, State, and ZIP Code)
Lyndonville, VT. 05851

Chemical Name
and Synonyms

Trade Name
and Synonyms
Bag Balm Anusopric Salve

Chemical Family
Formula
0.3% Hydroxyquinoline Sulfate in
a Petroleum-Lanolin Base

Section II - Hazardous Ingredients

Paints, Preservatives, and Solvents	%	TLV (Units)	Alloys and Metallic Coatings	%	TLV (Units)
Pigments	None		Base Metal	None	
Catalyst	None		Alloys	None	
Vehicle	None		Metallic Coatings	None	
Solvents	Petroleum-Lanolin Base	99.7	Filler Metal	None	
Additives	None		Plus Coating or Core Flux	None	
Others	None		Others	None	

Hazardous Mixtures of Other Liquids, Solids or Gases	%	TLV (Units)
	None	

Section III - Physical Data

Boiling Point (*F)	NA	Specific Gravity (H ₂ O=1)	0.87
Vapor Pressure (mm Hg.)	NA	Percent Volatile by Volume (%)	2.0 - 3.0%
Vapor Density (AIR=1)	NA	Evaporation Rate	=1) NA

Solubility in Water
None

Appearance and Odor
Semi-solid cream, lanolin odor

Section IV - Fire and Explosion Hazard Data

Flash Point (Method Used) Greater than 200°F (Tag Open Cup)	Flammable Limits NA	LeI NA	UeI NA
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Extinguishing Media
NA

Special Fire Fighting Procedures
NA

Unusual Fire and Explosion Hazards
None

Section V - Health Hazard Data

Threshold Limit Value

Skin Irritation (Rabbit) None

Effects of Overexposure

NA

Emergency First Aid Procedures

NA

Section VI - Reactivity Data

Stability	Unstable		Conditions to Avoid
	Stable	X	

Incompatibility (Materials to Avoid)

Strong Oxidizing Agents

Hazardous Decomposition Products

None

Hazardous Polymerization	May Occur		Conditions to Avoid
	Will Not Occur	X	

Section VII - Spill or Leak Procedures

Steps to be Taken in Case Material is Released or Spilled

NA

Waste Disposal Method

Municipal Sanitary Landfill

Section VIII - Special Protection Information

Respiratory Protection (Specify Type)

Not Required

Ventilation	Local Exhaust	Not Required	Special
	Mechanical (General)	Not Required	Other

Protective Gloves	Not Required	Eye Protection	Not Required
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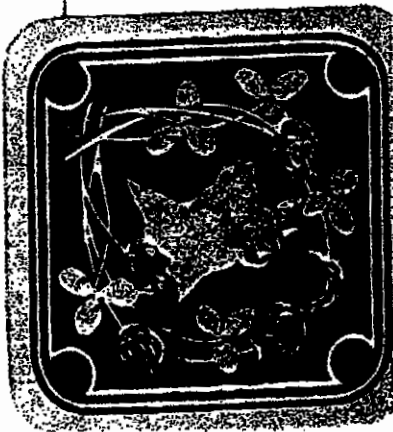
Other Protective Equipment
Not Required

Section IX - Special Precautions

Precautions to be Taken in Handling and Storing

None

Other Precautions
None



BAG BALM

MAKES TWO-GRADE AND QUALITY REMAINS FOR FULL SORTING EFFECT.

DAIRY ASSOCIATION CO., INC.
LYNDENVILLE, VT 05851

NET WEIGHT 10 OUNCES

SPECIAL DIRECTIONS

READ ALL DIRECTIONS CAREFULLY AND APPLY TO PROPER PARTS OF THE BODY. THE BAG BALM SHOULD BE APPLIED TO THE SKIN UNDER THE NAILS OF THE FINGERS AND TOOTH BRUSHES FOR THE BEST RESULTS. FOR THE BEST RESULTS, APPLY TO THE SKIN UNDER THE NAILS OF THE FINGERS AND TOOTH BRUSHES FOR THE BEST RESULTS. FOR THE BEST RESULTS, APPLY TO THE SKIN UNDER THE NAILS OF THE FINGERS AND TOOTH BRUSHES FOR THE BEST RESULTS.

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