

Safety Data Sheet

Exelderm Cream, 1%

SDS Revision Date:

03/12/2015

1. Identification

1.1. Product identifier

Product Identity

Exelderm Cream, 1%

Alternate Names

Exelderm Cream, 1%

1.2. Relevant identified uses of the substance or mixture and uses advised against

Intended use

See Technical Data Sheet.

Application Method

See Technical Data Sheet.

1.3. Details of the supplier of the safety data sheet

Company Name

OHM Laboratories
14 Terminal Road
New Brunswick, NJ, 08901

Emergency

CHEMTREC (USA)

(800) 424-9300

Customer Service: OHM Laboratories

Emergency Contact: Victor DeCandia
Phone: (732) 514-4743

2. Hazard(s) identification

2.1. Classification of the substance or mixture

No applicable GHS categories.

2.2. Label elements

Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.

No applicable GHS categories.

[Prevention]:

No GHS prevention statements

[Response]:

No GHS response statements

[Storage]:

No GHS storage statements

[Disposal]:

No GHS disposal statements

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3. Composition/information on ingredients

This product contains the following substances that present a hazard within the meaning of the relevant State and Federal Hazardous Substances regulations.

Ingredient/Chemical Designations	Weight %	GHS Classification	Notes
Propylene Glycol CAS Number: 0000057-55-6	25 - 50	Not Classified	[1]
octadecan-1-ol CAS Number: 0000112-92-5	1.0 - 10	Not Classified	[1]
Isopropyl myristate CAS Number: 0000110-27-0	1.0 - 10	Not Classified	[1]
Cetyl alcohol CAS Number: 0036653-82-4	1.0 - 10	Not Classified	[1]
SORBITAN, MONOOCTADECANOATE, POLY(OXY-1,2-ETHANEDI CAS Number: 0009005-67-8	1.0 - 10	Not Classified	[1]
Sorbitan monooleate CAS Number: 0001338-41-6	1.0 - 10	Not Classified	[1]
Sulconazole nitrate CAS Number: 0061318-91-0	1.0 - 10	Acute Tox. 4;H302	[1]

In accordance with paragraph (i) of §1910.1200, the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

[1] Substance classified with a health or environmental hazard.

[2] Substance with a workplace exposure limit.

[3] PBT-substance or vPvB-substance.

*The full texts of the phrases are shown in Section 16.

4. First aid measures

4.1. Description of first aid measures

General

In all cases of doubt, or when symptoms persist, seek medical attention.
Never give anything by mouth to an unconscious person.

Inhalation

Remove to fresh air, keep patient warm and at rest. If breathing is irregular or stopped, give artificial respiration. If unconscious place in the recovery position and obtain immediate medical attention. Give nothing by mouth.

Eyes

Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.

Skin

Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser.

Ingestion

If swallowed obtain immediate medical attention. Keep at rest. Do NOT induce vomiting.

4.2. Most important symptoms and effects, both acute and delayed

Overview

Eyes: Experimental data indicate that this material has low potential to cause eye reactions.

Skin: Blistering, burning, itching, erythema, redness, dermatitis, dry and cracking of skin

Experimental data indicate that this material has low potential to cause acute toxicity by ingestion.

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This material is a finished drug product for patient use. Material is a skin care product - lotion/oil. It is an antifungal agent. This product may cause: Blistering, burning, itching, erythema, redness, dermatitis, dry and cracking of skin, Material not fully tested.

5. Fire-fighting measures

5.1. Extinguishing media

Water spray, fog, dry chemical, alcohol foam, polymer foam, carbon dioxide

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition: Oxides of carbon and sulfur, formaldehyde gas, gaseous hydrogen chlorides and thiols.

5.3. Advice for fire-fighters

Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus.

ERG Guide No. ----

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Depending on the nature of the spill (quantity and extent of spill) additional protective clothing and equipment such as a self-contained breathing apparatus may be needed.

Put on appropriate personal protective equipment (see section 8).

6.2. Environmental precautions

Do not allow spills to enter drains or waterways.

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

6.3. Methods and material for containment and cleaning up

Containment Methods: Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations.

Cleanup Methods: Spill prevention procedures and a spill response procedure should be implemented. Contain and collect spillage and place in container for disposal according to local regulations. Handle waste materials, including gloves, protective clothing, contaminated spill cleanup material, etc., as appropriate for chemically and pharmacologically similar materials.

7. Handling and storage

7.1. Precautions for safe handling

Avoid exposure - obtain special instructions before use. Avoid contact with skin. Avoid inhalation of vapor or mist. Keep away from heat and sources of ignition. Prevent release to drains and waterways.

7.2. Conditions for safe storage, including any incompatibilities

Handle containers carefully to prevent damage and spillage.

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Incompatible materials: Strong oxidizers and alkali metals.

Store at room temperature in the original container. Exposures to temperatures exceeding 40°C should be avoided. Protect against light. Keep away from heat, sparks and flames. Store at room temperature in the original container

7.3. Specific end use(s)

No data available.

8. Exposure controls and personal protection

8.1. Control parameters

		Exposure	
CAS No.	Ingredient	Source	Value
0000057-55-6	Propylene Glycol	OSHA	No Established Limit
		ACGIH	TWA(Aerosol): 10 mg/m3
		NIOSH	No Established Limit
		Supplier	10 mg/m3 TWA (listed as AIHA WEEL)
0000110-27-0	Isopropyl myristate	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit
0000112-92-5	octadecan-1-ol	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit
0001338-41-6	Sorbitan monooleadecanoate	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit
0009005-67-8	SORBITAN, MONOOCTADECANOATE, POLY(OXY-1,2-ETHANEDI	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit
0036653-82-4	Cetyl alcohol	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit
0061318-91-0	Sulconazole nitrate	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit

Carcinogen Data

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CAS No.	Ingredient	Source	Value
0000057-55-6	Propylene Glycol	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0000110-27-0	Isopropyl myristate	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0000112-92-5	octadecan-1-ol	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0001338-41-6	Sorbitan monooleate	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0009005-67-8	SORBITAN, MONOOCTADECANOATE, POLY(OXY-1,2-ETHANEDI	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0036653-82-4	Cetyl alcohol	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0061318-91-0	Sulconazole nitrate	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;

8.2. Exposure controls

Respiratory

Respiratory protection is not required for normal use of this material. If the occupational exposure limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Eyes

Glasses or chemical splash goggles are recommended if eye contact is possible. Chemical splash resistant goggles should be worn when potential for splash exists.

Skin

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place. Impervious nitrile, rubber and latex gloves are recommended. Please note that employees who are allergic to natural rubber latex should use nitrile gloves.

Engineering Controls

When handling small quantities in a clinical setting, good room ventilation is desirable. Specific engineering controls should not be needed. When handling larger quantities, such as in a manufacturing setting, ensure worker exposure is below the recommended exposure limit. If significant aerosol (mist) is generated, use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit.

Other Work Practices

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

See section 2 for further details. - [Prevention]:

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9. Physical and chemical properties

Appearance	White to off white Liquid
Odor	Perfumed
Odor threshold	Not Measured
pH	Not Measured
Melting point / freezing point	Not Measured
Initial boiling point and boiling range	Not Measured
Flash Point	Not Measured
Evaporation rate (Ether = 1)	Not Measured
Flammability (solid, gas)	Not Applicable
Upper/lower flammability or explosive limits	Lower Explosive Limit: Not Measured Upper Explosive Limit: Not Measured
Vapor pressure (Pa)	Negligible
Vapor Density	(Air = 1) If adequate temperatures caused materials to volatilize, its vapor density would be much greater than 1. (Heavier than air)
Specific Gravity	Not Measured
Solubility in Water	Slight
Partition coefficient n-octanol/water (Log Kow)	Not Measured
Auto-ignition temperature	Not Measured
Decomposition temperature	Not Measured
Viscosity (cSt)	Greater than water, cream

9.2. Other information

No other relevant information.

10. Stability and reactivity

10.1. Reactivity

Hazardous Polymerization will not occur.

10.2. Chemical stability

Stable under normal circumstances.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Temperatures above 160 C

10.5. Incompatible materials

Strong oxidizers and alkali metals.

10.6. Hazardous decomposition products

Oxides of carbon and sulfur, formaldehyde gas, gaseous hydrogen chloride, and thiols.

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11. Toxicological information

Acute toxicity

Ingredient	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapor LC50, mg/L/4hr	Inhalation Dust/Mist LC50, mg/L/4hr	Inhalation Gas LC50, ppm
Propylene Glycol - (57-55-6)	20,000.00, Rat - Category: NA	20,800.00, Rabbit - Category: NA	105.00, Rat - Category: NA	No data available	No data available
octadecan-1-ol - (112-92-5)	No data available	No data available	No data available	No data available	No data available
Isopropyl myristate - (110-27-0)	No data available	No data available	No data available	No data available	No data available
Cetyl alcohol - (36653-82-4)	No data available	No data available	No data available	No data available	No data available
SORBITAN, MONOOCTADECANOATE, POLY(OXY- 1,2-ETHANEDI - (9005-67-8)	No data available	No data available	No data available	No data available	No data available
Sorbitan monooleate - (1338-41-6)	No data available	No data available	No data available	No data available	No data available
Sulconazole nitrate - (61318-91-0)	1,741.00, Rat - Category: 4	No data available	No data available	No data available	No data available

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

Reproductive Toxicity Sulconazole nitrate

Reproductive Toxicity

Oral Reproductive and developmental study (rat)

(parent, females) Maternal effects include: vaginal discharge, altered pregnancy duration, death during birth.

Oral Reproductive and developmental study (rabbit)

(parent, females) LOAEL = 3 mg/kg

Maternal effects include: altered pregnancy duration, difficult birth.

Oral Study of Fertility and Early Embryonic Development (rat)

(parent, males) NOAEL = 100 mg/kg

No effects were found on mating or fertility. (male)

subcutaneous Reproductive and developmental study (rat)

LOAEL = 10 mg/kg

Maternal effects include: decreased fertility, embryo toxicity. Paternal effects include: decreased fertility.

subcutaneous Reproductive and developmental study (rabbit)

(parent, males) LOAEL = 10 mg/kg

Maternal effects include: embryo toxicity, decreased fertility. Paternal effects include: decreased fertility.

Assessment Reproductive Toxicity

Animal studies indicate that reproductive effects can occur.

Developmental Toxicity Sulconazole nitrate

Oral Study of Embryo-Fetal Development (rat)

NOAEL = 50 mg/kg.

Did not show teratogenic effects in animal experiments.

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Oral Study of Embryo-Fetal Development (rabbit)

NOAEL = 50 mg/kg.

Did not show teratogenic effects in animal experiments.

Study of Pre- and Postnatal Development (rat)

Maternal effects include: altered pregnancy duration, difficult birth.

Developmental Toxicity Assessment

Did not show teratogenic effects in animal experiments.

Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	---	Not Applicable
Skin corrosion/irritation	---	Not Applicable
Serious eye damage/irritation	---	Not Applicable
Respiratory sensitization	---	Not Applicable
Skin sensitization	---	Not Applicable
Germ cell mutagenicity	---	Not Applicable
Carcinogenicity	---	Not Applicable
Reproductive toxicity	---	Not Applicable
STOT-single exposure	---	Not Applicable
STOT-repeated exposure	---	Not Applicable
Aspiration hazard	---	Not Applicable

12. Ecological information

12.1. Toxicity

No additional information provided for this product. See Section 3 for chemical specific data.

Aquatic Ecotoxicity

Ingredient	96 hr LC50 fish, mg/l	48 hr EC50 crustacea, mg/l	ErC50 algae, mg/l
Propylene Glycol - (57-55-6)	40,613.00, Oncorhynchus mykiss	18,340.00, Ceriodaphnia dubia	19,000.00 (96 hr), Pseudokirchneriella subcapitata
octadecan-1-ol - (112-92-5)	Not Available	Not Available	Not Available
Isopropyl myristate - (110-27-0)	Not Available	Not Available	Not Available
Cetyl alcohol - (36653-82-4)	Not Available	Not Available	Not Available
SORBITAN, MONOOCTADECANOATE, POLY(OXY-1,2-ETHANEDI - (9005-67-8)	Not Available	Not Available	Not Available
Sorbitan monooleate - (1338-41-6)	Not Available	Not Available	Not Available
Sulconazole nitrate - (61318-91-0)	Not Available	Not Available	Not Available

12.2. Persistence and degradability

There is no data available on the preparation itself.

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12.3. Bioaccumulative potential

Not Measured

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

12.6. Other adverse effects

No data available.

13. Disposal considerations

13.1. Waste treatment methods

Observe all federal, state and local regulations when disposing of this substance.

14. Transport information

	DOT (Domestic Surface Transportation)	IMO / IMDG (Ocean Transportation)	ICAO/IATA
14.1. UN number	Not Applicable	Not Regulated	Not Regulated
14.2. UN proper shipping name	Not Regulated	Not Regulated	Not Regulated
14.3. Transport hazard class(es)	DOT Hazard Class: Not Applicable	IMDG: Not Applicable Sub Class: Not Applicable	Air Class: Not Applicable
14.4. Packing group	Not Applicable	Not Applicable	Not Applicable
14.5. Environmental hazards			
IMDG	Marine Pollutant: No		
14.6. Special precautions for user	No further information		

15. Regulatory information

Regulatory Overview	The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.
Toxic Substance Control Act (TSCA)	All components of this material are either listed or exempt from listing on the TSCA Inventory.
WHMIS Classification	Not Regulated
US EPA Tier II Hazards	Fire: No Sudden Release of Pressure: No Reactive: No Immediate (Acute): No Delayed (Chronic): No

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EPCRA 311/312 Chemicals and RQs:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

EPCRA 302 Extremely Hazardous:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

EPCRA 313 Toxic Chemicals:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Carcinogens (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Developmental Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Female Repro Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Male Repro Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

New Jersey RTK Substances (>1%):

Propylene Glycol

Pennsylvania RTK Substances (>1%):

Propylene Glycol

16. Other information

The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

The full text of the phrases appearing in section 3 is:

H302 Harmful if swallowed.

This is the first version in the GHS SDS format. Listings of changes from previous versions in other formats are not applicable.

Therapeutic agents are intended for use under direction of a physician and/or under the conditions described on the label. As a general precaution, personnel who handle drug substances should avoid contact (ingestion, inhalation, skin and eye contact) with these substances. This Safety Data Sheet is intended for use by personnel who handle this material as part of their job responsibilities. It does not address the therapeutic use of this material. Information concerning the therapeutic use of this drug substance should be obtained from formulated product packaging inserts and other appropriate references. The information contained in this SDS is believed to be accurate and represents the best information reasonably available at the time of preparation. However, we make no warranty, express or implied, with respect to such information and we assume no liability from its use.

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