

SAFETY DATA SHEETS

This SDS packet was issued with item:

078912598

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

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The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078912597

1. Identification

Product identifier	Surolan
Other means of identification	
Item Code	CA0813
Synonyms	1H-Imidazole, 1-[2-(2,4-dichlorophenyl)-2-[(2,4-dichlorophenyl)methoxy]ethyl]-, mononitrate
Recommended use	Veterinary Pharmaceutical
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Manufacturer	
Company Name	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140 US
Phone:	1-877-Elanco1 (1-877-352-6261)
Email:	lilly_msds@lilly.com
Emergency Telephone Numbers:	Elanco Product Technical Support / Human or Animal Exposure Reporting: 1-888-545-5973 Transportation Emergency Telephone: CHEMTREC: 1-800-424-9300 (Outside U.S. 1-703-527-3887)

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Germ cell mutagenicity	Category 2
	Reproductive toxicity	Category 2
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Warning
Hazard statement	
H341	Suspected of causing genetic defects.
H361	Suspected of damaging fertility or the unborn child.

Precautionary statement

Prevention

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P281	Use personal protective equipment as required.

Response

P308 + P313	IF exposed or concerned: Get medical advice/attention.
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Storage

P405	Store locked up.
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Disposal

P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
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Hazard(s) not otherwise classified (HNOC)	None known.
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3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Miconazole nitrate	1H-Imidazole, 1-[2-(2,4-dichlorophenyl)-2-[(2,4-dichlorophenyl)methoxy]ethyl]-, mononitrate	22832-87-7	2.3
Colloidal anhydrous silica		7631-86-9	0.75
Prednisolone acetate		52-21-1	0.5
Other components below reportable levels			96.45

4. First-aid measures

Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. Call a physician or poison control center immediately.
Skin contact	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Get medical attention if irritation develops and persists.
Eye contact	In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention if irritation develops and persists.
Ingestion	Call a physician or poison control center immediately. Rinse mouth. Never give anything by mouth to a victim who is unconscious or is having convulsions.
Most important symptoms/effects, acute and delayed	May cause adverse reproductive effects - such as birth defects, miscarriages, or infertility based on animal data.
Indication of immediate medical attention and special treatment needed	Treat symptomatically.
General information	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). IF exposed or concerned: Get medical advice/attention.

5. Fire-fighting measures

Suitable extinguishing media	Foam. Carbon dioxide (CO2). Water. Sand.
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	Fire or excessive heat may produce hazardous decomposition products.
Special protective equipment and precautions for firefighters	Wear self-contained breathing apparatus and protective clothing.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Prevent further migration into the environment. Use absorbent/adsorbent material to solidify liquids. Collect in a non-combustible container for prompt disposal. Clean surface thoroughly to remove residual contamination. Large spills due to traffic accidents, etc., should be reported immediately to CHEMTREC and Elanco Animal Health for assistance.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground. Avoid release to the environment.

7. Handling and storage

Precautions for safe handling

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash hands thoroughly after handling. Avoid breathing dust/fume/gas/mist/vapors/spray.

Conditions for safe storage, including any incompatibilities

Do not store in open or unlabelled containers. Store locked up.

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value
Colloidal anhydrous silica (CAS 7631-86-9)	TWA	0.8 mg/m ³
		20 mppcf

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Colloidal anhydrous silica (CAS 7631-86-9)	TWA	6 mg/m ³

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

Supplier: 0.75 mg/m³ TWA (Miconazole Nitrate)

A Lilly exposure guideline has not been established. The above exposure guideline has been established by the supplier.

Appropriate engineering controls

Open handling is not recommended. Use appropriate control measures such as fume hood, ventilated enclosure, local exhaust ventilation, or down-draft booth.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear goggles/face shield.

Skin protection

Hand protection

Wear appropriate chemical resistant gloves.

Other

Chemical-resistant gloves and impermeable body covering to minimize skin contact.

Respiratory protection

In case of insufficient ventilation, wear suitable respiratory equipment. Respirator with a full face mask.
ABEK
P3

Thermal hazards

Not applicable.

9. Physical and chemical properties

Appearance

Physical state

Liquid.

Form

Liquid. Suspension.

Color

White

Odor

Odorless

Odor threshold

No data available.

pH

No data available.

Melting point/freezing point

No data available.

Initial boiling point and boiling range

No data available.

Flash point

No data available.

Evaporation rate

No data available.

Flammability (solid, gas)

Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

No data available.

Flammability limit - upper (%)	No data available.
Explosive limit - lower (%)	No data available.
Explosive limit - upper (%)	No data available.
Vapor pressure	No data available.
Vapor density	No data available.
Relative density	No data available.
Solubility(ies)	
Solubility (water)	No data available.
Partition coefficient (n-octanol/water)	No data available.
Auto-ignition temperature	No data available.
Decomposition temperature	No data available.
Viscosity	No data available.
Other information	
Density	No data available.
Dissociation constant	No data available.
Drop point	No data available.
Explosive limit	No data available.
Explosive properties	Not explosive
Explosivity	No data available.
Flame extension	No data available.
Flame projection	No data available.
Flammability	No data available.
Flammability (flash back)	No data available.
Oxidizing properties	The substance or mixture is not classified as oxidizing.
Potential for dust explosion	No data available.
VOC (Weight %)	No data available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Fire or excessive heat may produce hazardous decomposition products.

11. Toxicological information

Information on toxicological effects

Acute toxicity Based on available data, the classification criteria are not met.

Components	Species	Test Results
Colloidal anhydrous silica (CAS 7631-86-9)		
Acute		
Dermal		
LD50	Rabbit	> 5000 mg/kg

Components	Species	Test Results
Inhalation		
<i>Dust</i>		
LC50	Rat	> 58.8 mg/l, 4 hours
Oral		
LD50	Rat	> 5000 mg/kg
Miconazole nitrate (CAS 22832-87-7)		
<u>Acute</u>		
Oral		
LD	Rat	> 640 mg/kg
LD50	Dog	> 160 mg/kg
	Guinea pig	> 275.9 mg/kg
	Mouse	> 578.1 mg/kg
	Rat	920 mg/kg
		550 mg/kg
Skin corrosion/irritation	Due to partial or complete lack of data the classification is not possible.	
Serious eye damage/eye irritation	Due to partial or complete lack of data the classification is not possible.	
Respiratory or skin sensitization		
Respiratory sensitization	Due to partial or complete lack of data the classification is not possible.	
Skin sensitization	Due to partial or complete lack of data the classification is not possible.	
Germ cell mutagenicity	Suspected of causing genetic defects. Induced chromosome aberrations in vivo. (Miconazole Nitrate)	
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Colloidal anhydrous silica (CAS 7631-86-9)		3 Not classifiable as to carcinogenicity to humans.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)		
Not listed.		
Reproductive toxicity	Oral studies in rats and rabbits given up to 100 mg/kg during gestation did not produce teratogenic effects in offspring. Significant prolonged gestation was observed in rats orally given more than 30 mg/kg/day. Increased fetal resorption observed in rabbits given 100 mg//kg/day along with decreased maternal body weight.	
Specific target organ toxicity - single exposure	Due to partial or complete lack of data the classification is not possible.	
Specific target organ toxicity - repeated exposure	Due to partial or complete lack of data the classification is not possible.	
Aspiration hazard	No aspiration toxicity classification	

12. Ecological information

Ecotoxicity Toxic to aquatic life with long lasting effects.

Components		Species	Test Results
Colloidal anhydrous silica (CAS 7631-86-9)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 24 hours
Fish	LCL0	Zebra danio (Danio rerio)	10000 mg/l, 96 hours
Miconazole nitrate (CAS 22832-87-7)			
Other	EC50	Activated sludge of a predominantly domestic sewage	> 1 mg/l, 3 h
Chronic			
Other	NOEC	Activated sludge of a predominantly domestic sewage	>= 1 mg/l, 3 h

Components		Species	Test Results
Aquatic			
Crustacea	NOEC	Daphnia	0.045 mg/l
<i>Acute</i>			
Algae	EC50	Freshwater algae	0.03 mg/l Growth inhibition. 0.019 mg/l Cell multiplication. 0.01 mg/l Growth inhibition. (Scenedesmus capricornutum)
Crustacea	EC50	Daphnia	0.119 mg/l
Fish	EC50	Zebra danio (Danio rerio)	0.144 mg/l
<i>Chronic</i>			
Algae	NOEC	Freshwater algae	0.01 mg/l 0.001 mg/l
Fish	LOEC	Rainbow trout,donaldson trout (Oncorhynchus mykiss)	0.44 mg/l, 28 d
		Zebra danio (Danio rerio)	0.036 mg/l, 21 d
	NOEC	Rainbow trout,donaldson trout (Oncorhynchus mykiss)	0.02 mg/l, 28 d
		Zebra danio (Danio rerio)	0.028 mg/l 0.012 mg/l, 21 d

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available on bioaccumulation.

Partition coefficient n-octanol / water (log Kow)

Miconazole nitrate

3.4 Test method not available.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations.

14. Transport information

General information Effective January 1, 2015 by Special Provision, UN3077 and UN3082 when packaged in inner packages of 5L / 5 KG or less are not subject to the dangerous goods regulations.

DOT

Not regulated as dangerous goods.

IATA

UN number UN3082
UN proper shipping name Environmentally hazardous substance, liquid, n.o.s. (Miconazole nitrate)
Transport hazard class(es)
Class 9
Subsidiary risk -
Packing group III
Environmental hazards Yes
ERG Code 9L
Special precautions for user Read safety instructions, SDS and emergency procedures before handling.
Other information
Passenger and cargo aircraft Allowed.
Cargo aircraft only Allowed.

IMDG

UN number UN3082

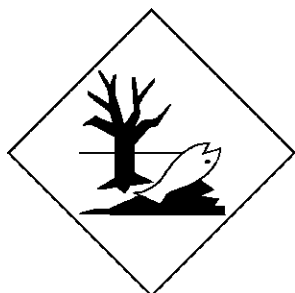
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Miconazole nitrate)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	
Marine pollutant	Yes
EmS	F-A, S-F
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

IATA; IMDG



Marine pollutant



15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes
 Delayed Hazard - Yes
 Fire Hazard - No
 Pressure Hazard - No
 Reactivity Hazard - No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.**US state regulations****US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

US. Massachusetts RTK - Substance List

Colloidal anhydrous silica (CAS 7631-86-9)

US. New Jersey Worker and Community Right-to-Know Act

Colloidal anhydrous silica (CAS 7631-86-9)

US. Pennsylvania Worker and Community Right-to-Know Law

Colloidal anhydrous silica (CAS 7631-86-9)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision**Issue date** 03-31-2015**Version #** 01**Lilly Lab Code** Health: 1
Fire: 1
Reactivity: 0**List of abbreviations**

TWA: Time Weighted Average

Disclaimer

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Elanco Animal Health
0011+1-877-352-6261
0011+1-800-428-4441**Revision Information**Product and Company Identification: Product Codes
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties
Toxicological Information: Toxicological Data
Ecological Information: Ecotoxicity
Transport Information: Proper Shipping Name/Packing Group
Regulatory Information: Risk Phrases - Labeling
GHS: Classification



SAFETY DATA SHEET

1. Identification

Product identifier Surolan Suspension for Otitis Externa and Skin Infections in Dogs and Cats

Other means of identification

Item Code CA0813

Recommended use Veterinary Pharmaceutical

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Company Name Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140
US

Phone: 1-877-Elanco1 (1-877-352-6261)

Emergency Telephone: Elanco Product Technical Support / Human or Animal Exposure Reporting:
1-888-545-5973

Email: elanco_sds@elanco.com

Transportation Emergency Telephone: CHEMTREC: 1-800-424-9300
(Outside U.S. 1-703-527-3887)

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards

Germ cell mutagenicity	Category 2
Reproductive toxicity	Category 1B
Reproductive toxicity	Effects on or via lactation
Aspiration hazard	Category 1

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement

H341	Suspected of causing genetic defects.
H360	May damage fertility or the unborn child.
H362	May cause harm to breast-fed children.
H304	May be fatal if swallowed and enters airways.

Precautionary statement

Prevention

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe mist/vapors.
P263	Avoid contact during pregnancy and while nursing.
P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

Response

P301 + P310	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
P331	Do NOT induce vomiting.
P308 + P313	IF exposed or concerned: Get medical advice/attention.

Storage	
P405	Store locked up.
Disposal	
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Liquid Paraffin		64742-56-9	96.38
Miconazole nitrate	1H-Imidazole, 1-[2-(2,4-dichlorophenyl)-2-[(2,4-dichlorophenyl)methoxy]ethyl]-, mononitrate	22832-87-7	2.3
Prednisolone acetate		52-21-1	0.5

Composition comments Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed	Suspected of causing genetic defects. May damage fertility or the unborn child. May cause harm to breast-fed children. May be fatal if swallowed and enters airways.
Indication of immediate medical attention and special treatment needed	Treat symptomatically. Symptoms may be delayed.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust. Local authorities should be advised if significant spillages cannot be contained. See Section 8 of the SDS for Personal Protective Equipment.
Methods and materials for containment and cleaning up	Small Spillages: Do not sweep. Vacuum material with appropriate dust collection filter in place. If vacuum is not available, lightly mist/wet material and remove by mopping or wet wiping. Prevent further migration into the environment. Large spills due to traffic accidents, etc., should be reported immediately to CHEMTREC and Elanco Animal Health for assistance. Local authorities should be advised if significant spillages cannot be contained.
Environmental precautions	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes.

7. Handling and storage

Precautions for safe handling	Avoid prolonged exposure. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container.

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Liquid Paraffin (CAS 64742-56-9)	PEL	5 mg/m3	Mist.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Liquid Paraffin (CAS 64742-56-9)	TWA	5 mg/m3	Inhalable fraction.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Liquid Paraffin (CAS 64742-56-9)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Wear safety glasses with side shields (or goggles).
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves.
Other	Wear suitable protective clothing.
Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment.
Thermal hazards	Not available.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Physical state	Liquid.
Form	Suspension.
Color	White
Odor	Odorless
Odor threshold	No data available.
pH	No data available.
Melting point/freezing point	No data available.
Initial boiling point and boiling range	No data available.
Flash point	No data available.
Evaporation rate	No data available.
Flammability (solid, gas)	Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	No data available.
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Flammability limit - upper (%)	No data available.
Explosive limit - lower (%)	No data available.
Explosive limit - upper (%)	No data available.
Vapor pressure	No data available.
Vapor density	No data available.
Relative density	No data available.
Solubility(ies)	
Solubility (water)	No data available.
Partition coefficient (n-octanol/water)	No data available.
Auto-ignition temperature	No data available.
Decomposition temperature	No data available.
Viscosity	No data available.
Other information	
Density	No data available.
Explosive properties	Not explosive.
Flammability	No data available.
Oxidizing properties	Not oxidizing.
Potential for dust explosion	No data available.
VOC	No data available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents. Peroxides. Phenols.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on toxicological effects

Acute toxicity Based on available data, the classification criteria are not met.

Product	Species	Test Results
Surolan Suspension for Otitis Externa and Skin Infections in Dogs and Cats		
<u>Acute</u>		
Oral		
LD50	Rat	550 mg/kg
Components	Species	Test Results
Liquid Paraffin (CAS 64742-56-9)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	> 5000 mg/kg
Inhalation		
LC50	Rat	5000 mg/m3, 4 h
Oral		
LD50	Rat	> 5000 mg/kg

Components	Species	Test Results
Miconazole nitrate (CAS 22832-87-7)		
<u>Acute</u>		
Oral		
LD50	Rat	920 mg/kg
Prednisolone acetate (CAS 52-21-1)		
Oral		
LD50	Mouse	1680 mg/kg
Skin corrosion/irritation	Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.	
Respiratory or skin sensitization		
Respiratory sensitization	Based on available data, the classification criteria are not met.	
Skin sensitization	Based on available data, the classification criteria are not met.	
Germ cell mutagenicity	Suspected of causing genetic defects. (Miconazole Nitrate)	
Carcinogenicity	Based on available data, the classification criteria are not met.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not listed.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)		
Not regulated.		
US. National Toxicology Program (NTP) Report on Carcinogens		
Liquid Paraffin (CAS 64742-56-9)	Known To Be Human Carcinogen.	
Reproductive toxicity	May damage fertility or the unborn child. May cause harm to breastfed babies. (Prednisolone Acetate)	
Specific target organ toxicity - single exposure	Based on available data, the classification criteria are not met.	
Specific target organ toxicity - repeated exposure	Based on available data, the classification criteria are not met.	
Aspiration hazard	May be fatal if swallowed and enters airways. (Liquid Paraffin)	

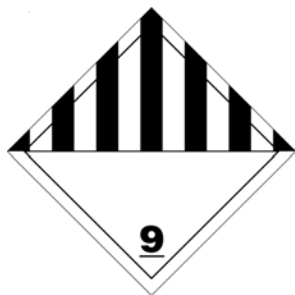
12. Ecological information

Ecotoxicity Toxic to aquatic life with long lasting effects.

Components	Species	Test Results
Liquid Paraffin (CAS 64742-56-9)		
Aquatic		
Algae	LC50	Algae > 100 mg/l
Crustacea	LC50	Daphnia > 100 mg/l
Fish	LC50	Fish > 100 mg/l
Miconazole nitrate (CAS 22832-87-7)		
Other	EC50	Activated sludge of a predominantly domestic sewage > 1000 mg/l, 3 h
	NOEC	Activated sludge of a predominantly domestic sewage >= 1000 mg/l, 3 h
Aquatic		
Algae	EC50	Algae 0.03 mg/l, 72 h
Crustacea	EC50	Daphnia magna 0.119 mg/l, 48 h
	NOEC	Daphnia magna 0.045 mg/l, 48 h
Fish	EC50	Danio rerio 0.144 mg/l, 96 h
	LOEC	Danio rerio 0.026 mg/l, 21 d
		Oncorhynchus mykiss 0.044 mg/l, 28 d
	NOEC	Danio rerio 0.028 mg/l, 96 h
		0.012 mg/l, 21 d

Components	Species	Test Results	
Prednisolone acetate (CAS 52-21-1)	Oncorhynchus mykiss	0.02 mg/l, 28 d	
Aquatic			
Crustacea	EC50	Daphnia	> 85 mg/l, 24 h
Fish	LC50	Fish	> 500 mg/l
Persistence and degradability	No data is available on the degradability of this product.		
Bioaccumulative potential	No data available on bioaccumulation.		
Partition coefficient n-octanol / water (log Kow)			
Miconazole nitrate	3.4 Test method not available.		
Bioconcentration factor (BCF)			
Miconazole nitrate	1949		
Mobility in soil	No data available.		
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.		
13. Disposal considerations			
Disposal instructions	Dispose of contents/container in accordance with local/regional/national/international regulations.		
14. Transport information			
General information	Effective January 1, 2015 by Special Provision, UN3077 and UN3082 when packaged in inner packages of 5L / 5 KG or less are not subject to the dangerous goods regulations.		
DOT			
Not regulated as dangerous goods.			
IATA			
UN number	UN3082		
UN proper shipping name	Environmentally hazardous substance, liquid, n.o.s. (Miconazole nitrate)		
Transport hazard class(es)			
Class	9		
Subsidiary risk	-		
Packing group	III		
Environmental hazards	Yes		
ERG Code	9L		
Special precautions for user	Not available.		
Other information			
Passenger and cargo aircraft	Allowed with restrictions.		
Cargo aircraft only	Allowed with restrictions.		
IMDG			
UN number	UN3082		
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Miconazole nitrate)		
Transport hazard class(es)			
Class	9		
Subsidiary risk	-		
Packing group	III		
Environmental hazards			
Marine pollutant	Yes		
EmS	F-A, S-F		
Special precautions for user	Not available.		
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not established.		

IATA; IMDG



Marine pollutant



15. Regulatory information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Classified hazard categories

Germ cell mutagenicity
Reproductive toxicity
Aspiration hazard

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

US state regulations

California Proposition 65

For more information go to www.P65Warnings.ca.gov.

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

Liquid Paraffin (CAS 64742-56-9)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	12-18-2018
Revision date	02-05-2019
Version #	03

List of abbreviations	EC50: Effective Concentration 50%. LC50: Lethal Concentration 50%. LD: Lethal Dose. LD50: Lethal Dose 50%. LOEC: Lowest observable effect concentration. NOAEL: No observed adverse effect level. NOEC: No observed effect concentration. PEL: Permissible Exposure Limit. STEL: Short-Term Exposure Limit. TLV: Threshold Limit Value.
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Disclaimer	<p>As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.</p>
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