

SAFETY DATA SHEETS

This SDS packet was issued with item:

078912597

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

078782446 078782453

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).

078912598

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

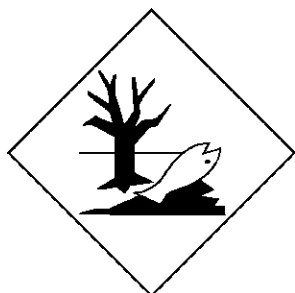
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Miconazole nitrate)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	
Marine pollutant	Yes
EmS	F-A, S-F
Special precautions for user	Read safety instructions, SDS and emergency procedures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

Synonyms 1H-Imidazole, 1-[2-(2,4-dichlorophenyl)-2-[(2,4-dichlorophenyl)methoxy]ethyl]-, mononitrate

Item Code CA0813

Recommended use of the chemical and restrictions on use

Recommended use Veterinary Pharmaceutical

Restrictions on use Not available.

Details of manufacturer or importer

Manufacturer

Company name Elanco Animal Health
A Division of Eli Lilly Australia Pty Ltd

Address A.B.N. 39 000 233 992
112 Wharf Road, West Ryde, N.S.W. 2114, Australia

Telephone (02) 9878 7777

Fax (02) 9878 7720

e-mail lilly_msds@lilly.com

Emergency phone number Elanco Animal Health: 1800 226 324 (Toll free)
OR Poisons Information Centre: 131126 (Australia-wide)

24 hr emergency contact number CHEMWATCH 1800 039 008 (spills and accidents)

24 hr emergency contact number (Local) CHEMWATCH +61 2 9186 1132 (spills and accidents)

2. Hazard(s) identification

Classification of the hazardous chemical

Physical hazards Not classified.

Health hazards Germ cell mutagenicity Category 2

Environmental hazards Hazardous to the aquatic environment, acute hazard Category 2
Hazardous to the aquatic environment, long-term hazard Category 2

Label elements, including precautionary statements

Hazard symbol(s)



Health hazard Environment

Signal word Warning

Hazard Statement(s) Suspected of causing genetic defects. Toxic to aquatic life with long lasting effects.

Precautionary Statement(s)

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

Response IF exposed or concerned: Get medical advice/attention.

Storage Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Other hazards which do not result in classification None known.

Supplemental information None.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
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
Other components below reportable levels		97.2

4. First-aid measures

Description of necessary first aid measures

Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. Call a physician or poison control centre 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 centre immediately. Rinse mouth. Never give anything by mouth to a victim who is unconscious or is having convulsions.
Personal protection for first-aid responders	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.
Symptoms caused by exposure	May cause adverse reproductive effects - such as birth defects, miscarriages, or infertility based on animal data.
Medical attention and special treatment	Treat symptomatically.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Foam. Carbon dioxide (CO ₂). 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 fire fighters Wear self-contained breathing apparatus and protective clothing.

Fire fighting equipment/instructions Move containers from fire area if you can do so without risk.

Hazchem Code 3Z

General fire hazards No unusual fire or explosion hazards noted.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. For personal protection, see section 8.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground. Avoid release to the environment.

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 CHEMWATCH and Elanco Animal Health for assistance.

Other issues relating to spills and releases Clean up in accordance with all applicable regulations.

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/vapours/spray.

Conditions for safe storage, including any incompatibilities Do not store in open or unlabelled containers. Store locked up.

8. Exposure controls and personal protection

Control parameters 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.

Occupational exposure limits No exposure limits noted for ingredient(s).

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, for example personal protective equipment (PPE)

Eye/face protection Wear goggles/face shield. (AS/NZS 1337)

Skin protection

Hand protection Wear appropriate chemical resistant gloves. (AS 2161)

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
(AS/NZS 1715)

Thermal hazards Not applicable.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Liquid. Suspension.

Colour White

Odour Odourless.

Odour 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.

Vapour pressure No data available.

Vapour 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 physical and chemical parameters

Density No data available.

Dissociation constant No data available.

Dropping 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.

Oxidising 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 oxidising agents.

Hazardous decomposition products Fire or excessive heat may produce hazardous decomposition products.

11. Toxicological information

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

Components	Species	Test results
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/irritation	Due to partial or complete lack of data the classification is not possible.	
Respiratory or skin sensitisation		
Respiratory sensitisation	Due to partial or complete lack of data the classification is not possible.	
Skin sensitisation	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.	
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. Based on available data, the classification criteria are not met.	
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
Miconazole nitrate (CAS 22832-87-7)			
Other	EC50	Activated sludge of a predominantly domestic sewage	> 1 mg/l, 3 h
<i>Chronic</i>			
Other	NOEC	Activated sludge of a predominantly domestic sewage	>= 1 mg/l, 3 h
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

Components		Species	Test results
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 for this product.

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 methods 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.

ADG

UN number 3082
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
Hazchem Code •3Z
Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

Not classified as dangerous goods when transported by road or rail in packaging or receptacles not exceeding 500 kg (L) according to ADG 7 SP AU01.

RID

UN number 3082
UN proper shipping name Environmentally hazardous substance, liquid, n.o.s. (Miconazole nitrate)
Transport hazard class(es)
Class 9
Subsidiary risk -
Label(s) 9
Packing group III
Environmental hazards Yes
Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

IATA

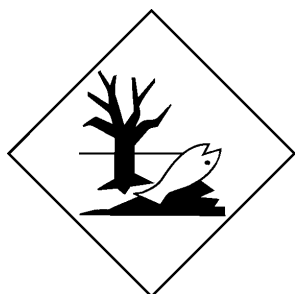
UN number 3082
UN proper shipping name Environmentally hazardous substance, liquid, n.o.s. (Miconazole nitrate)
Transport hazard class(es)
Class 9
Subsidiary risk -
Packing group III
Environmental hazards Yes

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	3082
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.

ADG; IATA; IMDG; RID



Marine pollutant



15. Regulatory information

Safety, health and environmental regulations

National regulations APVMA approval number 46427
Poison Schedule 4

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

Not listed.

Importation of Ozone Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations

This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	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

Issue date 29-September-2015
Key abbreviations or acronyms used 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.

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Revision Information Product and Company Identification: Alternate Trade Names
GHS: Classification