



# SAFETY DATA SHEET

## 1. Identification

**Product identifier**                                **Surolan**

**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.

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

<b>Inhalation</b>	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.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur.
<b>Most important symptoms/effects, acute and delayed</b>	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.
<b>Indication of immediate medical attention and special treatment needed</b>	Treat symptomatically. Symptoms may be delayed.

### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Use water spray to cool unopened containers.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	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.
<b>Methods and materials for containment and cleaning up</b>	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.
<b>Environmental precautions</b>	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. 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/m <sup>3</sup>	Mist.

#### US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Liquid Paraffin (CAS 64742-56-9)	TWA	5 mg/m <sup>3</sup>	Inhalable fraction.

#### US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Liquid Paraffin (CAS 64742-56-9)	STEL	10 mg/m <sup>3</sup>	Mist.
	TWA	5 mg/m <sup>3</sup>	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.

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

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization does not occur.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents. Peroxides. Phenols.
<b>Hazardous decomposition products</b>	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.

<b>Product</b>	<b>Species</b>	<b>Test Results</b>
Surolan		
<b><u>Acute</u></b>		
<b>Oral</b>		
LD50	Rat	550 mg/kg
<b>Components</b>		
<b><u>Acute</u></b>		
<b>Dermal</b>		
LD50	Rabbit	> 5000 mg/kg
<b>Inhalation</b>		
LC50	Rat	5000 mg/m <sup>3</sup> , 4 h
<b>Oral</b>		
LD50	Rat	> 5000 mg/kg

Components	Species	Test Results
Miconazole nitrate (CAS 22832-87-7)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	920 mg/kg
Prednisolone acetate (CAS 52-21-1)		
<b>Oral</b>		
LD50	Mouse	1680 mg/kg
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.	
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.	
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	Based on available data, the classification criteria are not met.	
<b>Skin sensitization</b>	Based on available data, the classification criteria are not met.	
<b>Germ cell mutagenicity</b>	Suspected of causing genetic defects. (Miconazole Nitrate)	
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.	
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>		
Not listed.		
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)</b>		
Not regulated.		
<b>US. National Toxicology Program (NTP) Report on Carcinogens</b>		
Liquid Paraffin (CAS 64742-56-9)	Known To Be Human Carcinogen.	
<b>Reproductive toxicity</b>	May damage fertility or the unborn child. May cause harm to breastfed babies. (Prednisolone Acetate)	
<b>Specific target organ toxicity - single exposure</b>	Based on available data, the classification criteria are not met.	
<b>Specific target organ toxicity - repeated exposure</b>	Based on available data, the classification criteria are not met.	
<b>Aspiration hazard</b>	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)		
<b>Aquatic</b>		
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
<b>Aquatic</b>		
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
	Oncorhynchus mykiss	0.02 mg/l, 28 d
Prednisolone acetate (CAS 52-21-1)		
<b>Aquatic</b>		
Crustacea	EC50	Daphnia > 85 mg/l, 24 h
Fish	LC50	Fish > 500 mg/l
<b>Persistence and degradability</b>	No data is available on the degradability of this product.	
<b>Bioaccumulative potential</b>	No data available on bioaccumulation.	
<b>Partition coefficient n-octanol / water (log Kow)</b>		
Miconazole nitrate		3.4 Test method not available.
<b>Bioconcentration factor (BCF)</b>		
Miconazole nitrate		1949
<b>Mobility in soil</b>	No data available.	
<b>Other adverse effects</b>	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.

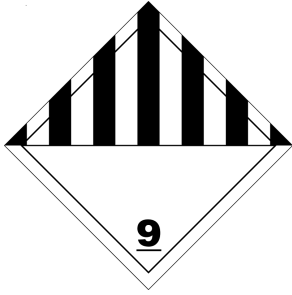
#### IATA

**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.

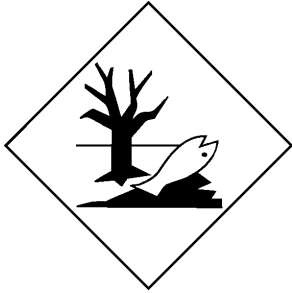
#### IMDG

**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](http://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** 03-31-2015

**Revision date** 02-05-2019

**Version #** 04

**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.

**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 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:  
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