



SAFETY DATA SHEET

1. Identification

Product identifier Itrafungol

Other means of identification
Item Code CA0796

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 Reproductive toxicity Category 1B

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement
H360 May damage 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.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

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

Storage Not available.

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	%
ITRACONAZOLE		84625-61-6	0.8

Remaining components are non-hazardous or below required reporting limits.

4. First-aid measures

Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. IF exposed or concerned: Get medical advice/attention.
Skin contact	Wash off immediately with soap and plenty of water. Get medical attention if irritation develops and persists.
Eye contact	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Never give anything by mouth to a victim who is unconscious or is having convulsions. Consult a physician.
Most important symptoms/effects, acute and delayed	May cause reproductive effects.
General information	If you feel unwell, seek medical advice (show the label where possible).

5. Fire-fighting measures

Suitable extinguishing media	Atomized water. Powder. Carbon dioxide (CO2). Foam. Sand
Unsuitable extinguishing media	Not available.
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.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Avoid contact with skin, eyes and clothing. Wear suitable protective clothing, gloves and eye/face protection.
Methods and materials for containment and cleaning up	Soak up with inert absorbent material. Transfer to a container for disposal.
Environmental precautions	Prevent further leakage or spillage if safe to do so. 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. Avoid contact with eyes, skin, and clothing.
Conditions for safe storage, including any incompatibilities	Keep container tightly closed in a dry and well-ventilated place. Store below 25°C.

8. Exposure controls/personal protection

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	Supplier: 0.4 mg/m ³ TWA 8 hour (Itraconazole) A Lilly exposure guideline has not been established. The above exposure guideline has been established by the supplier.
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	Safety glasses with side-shields.
Skin protection	
Hand protection	Use protective gloves.
Other	Protective gloves are recommended.
Respiratory protection	Under normal conditions, respirator is not normally required.
Thermal hazards	Not available.

General hygiene considerations

In a manufacturing setting, wear chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

When mixing and handling, use protective clothing, impervious gloves, and dust respirator (recommended). Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse with plenty of water.

9. Physical and chemical properties**Appearance**

Physical state	Liquid.
Form	Liquid.
Color	Light yellow
Odor	Cherry
Odor threshold	Not available.
pH	1.6 - 1.9 (100% concentration)
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	No data available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Oxidizing properties	The substance or mixture is not classified as oxidizing.

10. Stability and reactivity

Reactivity	Not water reactive.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	None known.
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**

Components	Species	Test Results
ITRACONAZOLE (CAS 84625-61-6)		
Acute		
Oral		
LD50	Rat	> 320 mg/kg
Other		
LD	Rat	40 mg/kg (intravenous injection)
Skin corrosion/irritation	Due to lack of data the classification is not possible.	
Serious eye damage/eye irritation	Due to lack of data the classification is not possible.	
Respiratory or skin sensitization		
Respiratory sensitization	Due to lack of data the classification is not possible.	
Skin sensitization	Due to lack of data the classification is not possible.	
Germ cell mutagenicity	In vitro and in vivo tests did not show mutagenic effects. (active ingredients) Based on available data, the classification criteria are not met.	
Carcinogenicity	Not listed by IARC, NTP, ACGIH or OSHA. No effects identified in animal studies. (Active ingredient(s)) 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		
Not listed.		
Reproductive toxicity	May damage the unborn child. (Active ingredient(s))	
Specific target organ toxicity - single exposure	Due to lack of data the classification is not possible.	
Specific target organ toxicity - repeated exposure	No significant target organ toxicity reported. (active ingredient) Based on available data, the classification criteria are not met.	
Aspiration hazard	Not applicable.	

12. Ecological information

Ecotoxicity

Components	Species	Test Results
ITRACONAZOLE (CAS 84625-61-6)		
<i>Acute</i>		
	EC50	> 2000 mg/l, 3 hours activated sludge
	NOEC	> 2000 mg/l, 3 hours activated sludge
Aquatic		
<i>Acute</i>		
Algae	EC50	Algae > 1000 mg/l, 10 days
Crustacea	EC50	Daphnia > 1000 mg/l, 48 hours
Fish	EC50	Bluegill (Lepomis macrochirus) > 1000 mg/l, 96 hours
Persistence and degradability	No data is available on the degradability of this product.	
Bioaccumulative potential	No data available.	
Partition coefficient n-octanol / water (log Kow)		
ITRACONAZOLE	15.3 (immobile)	
Mobility in soil	No data available for this product.	
Other adverse effects	Not available.	

13. Disposal considerations

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

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

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

15. Regulatory information

US federal regulations

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)

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.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
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	11-15-2016
Revision date	03-27-2019
Version #	02
List of abbreviations	TWA: Time Weighted Average

Disclaimer

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