SAFETY DATA SHEETS

This SDS packet was issued with item:

078706402

N/A

Product Name: Felimazole® (Coated tablets for cats)

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SECTION 1: IDENTIFICATION		
1.1 Product identifier		
Product name:	Felimazole® (Coated Tablets for cats) EU: 1.25mg, 2.5mg and 5mg US: 2.5mg and 5mg	
Synonyms:	Thiourelyne antithyroid agent	
Proper Shipping name:	Not applicable	
Other means of identification:	None	
1.2 Relevant identified uses	of the substances or mixture and uses advised against	
Recommended uses:	For use in cats. For the stabilisation of hyperthyroidism in cats prior to surgical thyroidectomy. For the long term treatment of feline hyperthyroidism.	
Uses advised against:	Not for human use. As thiamazole is a suspected human teratogen, pregnant women, and women of child-bearing age, should wear gloves when handling the product or the litter used by treated animals. Do not handle this product if you are allergic to hyperthyroidism inhibitors. • Do not use in cats suffering from systemic disease such as primary liver disease or diabetes mellitus. • Do not use in cats showing signs of autoimmune disease. • Do not use in animals with disorders of white blood cells, such as neutropenia and lymphopenia. • Do not use in animals with platelet disorders and coagulopathies (particularly thrombocytopenia). • Do not use in cats with hypersensitivity to thiamazole or the excipient, polyethylene glycol. Do not use in pregnant or lactating females.	
1.3 Details of the supplier o	f the substance or mixture	
Registered company name (UK):	Dechra Ltd	
	Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW UK	
Telephone:	+44 (0) 1756 791311	

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Fax:	+44 (0) 1756 798604
Website:	www.dechra.com
Email:	Not available
Registered company name (US):	Dechra Veterinary Products
Address:	Dechra Pharmaceutical Products 7015 College Blvd Suite 525 Overland Park KS 66211 USA
Telephone:	866-933-2472
Fax:	Not available
Website:	www.dechra.com
Email:	Not available
1.4 Emergency Telephone Numbers	
Dechra (US):	866-933-2472

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Considered a hazardous mixture according to Reg. (EC) No 1272/2008 and their amendments. Not classified as Dangerous Goods for transport purposes (EU).

Considered a Hazardous Substance by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200). Not classified as Dangerous Goods for transport purposes (US).

regulation (EC) No	 H302 - Acute Toxicity (Oral) Category 4 H341 - Gender Cell Mutagenic Substances of Category 2 H361 - Reproductive Toxicity 2 H335 - STOT - SE (No. Irr) Category 3
Legend:	Classified by Chemwatch
Classification (US):	Acute Toxicity (Oral) Category 4, Germ cell mutagenicity Category 2, Reproductive Toxicity Category 2, Specific target organ toxicity – single exposure Category 3 (respiratory tract irritation)
2.2 Label Elements	
GHS Label Elements:	

Signal Word: WARNING

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Hazard statement(s):	
, ,	Harmful if swallowed.
H341	Suspected of causing genetic defects.
	Suspected of damaging fertility or the unborn child.
H335	May cause respiratory irritation.
Precautionary Statement(s)	Prevention:
P201	Obtain special instructions before use.
P271	Use only outdoors or in a well-ventilated area.
P261	Avoid breathing dust/fumes.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P270	Do not eat, drink or smoke when using this product.
Precautionary Statement(s)	Response:
P308 + P313	IF exposed or concerned: Get medical advice/attention.
P301 + P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P330	Rinse mouth.
P304 + P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
Precautionary Statement(s)	Storage:
P405	Store locked up.
P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
Precautionary Statement(s) Disposal:	
P501	Dispose of contents/container in accordance with local regulations.

2.3 Other Hazard Information

Exposure may result in cumulative effects *. Exposure can cause irreversible effects *.

REACH - Art.57-59: The mixture contains no substances of highly hazardous substances (SVHC) on SDS date printing.

REACH (EU) Article 57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

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SECTION 3: INFORMATION ON THE INGREDIENTS

3.1 Substances

See section below for composition of mixtures

3.2 Mixtures			
1.CAS No 2.EC Number 3.Index Number 4.REACH Number	% Weight	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1. 60-56-0 2. 200-482-4 3. Not Available 4. Not Available	2.5-5	Thiamazole (EU) Methimazole (US)	Acute toxicity (oral) Category 4, gender cell mutagenic substance of category 2, reproductive toxicity 2; H302, H341, H361 ^[1]
	Balance	Ingredients determined not to be hazardous	
Legend:	1. Classified l	by Chemwatch	

SECTION 4: FIRST AID MEASURES	
4.1 Description of first a	nid measures
Eye contact:	Accidental spillage on the eyes should be washed off with plenty of water. If pain or irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
Skin contact:	Accidental spillage on the skin should be washed off with plenty of water. If irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner. Wash hands with soap and water after handling litter used by treated animals. As thiamazole is a suspected human teratogen, pregnant women, and women of child-bearing age, should wear gloves when handling the product or the litter used by treated animals.
Inhalation:	Inhalation is highly unlikely due to the nature of the product and how it is packaged and administered. If irritation or difficulty in breathing occurs, seek urgent medical advice and show the package leaflet or the label to the medical practitioner. Remove the patient from the contaminated area. Lay the patient down, keep warm and rested.
Ingestion:	IF SWALLOWED, SEEK MEDICAL ATTENTION WITHOUT DELAY. For advice, contact a Poisons Information Centre or a medical

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practitioner.

Urgent hospital treatment is likely to be needed. If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the SDS.

Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:

INDUCE vomiting with fingers down the back of the throat, **ONLY IF CONSCIOUS**. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

NOTE: Wear a protective glove when inducing vomiting by mechanical means.

4.2 Most important symptoms and effects, both acute and delayed

Thiamazole may cause vomiting, epigastric distress, headache, fever, arthralgia, pruritus and pancytopenia. Treatment is symptomatic.

For more information see Section 11

4.3 Indication of immediate medical attention and special treatment needed

If blood disorders such as agranulocytosis or bone-marrow depression occur exposure must cease immediately and if necessary, antibiotics and blood transfusions may be given.¹

Legend: MARTINDALE: The Extra Pharmacopoeia, 29th Edition

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable:	Select extinguishing media suitable for surrounding area.
Unsuitable:	There is no restriction on the type of extinguisher which may be used.

5.2 Special hazards arising from the substance or mixture

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5.3 Special protective actions for fire-fighters:	
Firefighting:	Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses. DO NOT approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location.
Fire / explosion hazard:	Non-combustible. Not considered a significant fire risk, however containers may burn. Decomposition may produce toxic fumes of: Sulphur oxides (SOx). May emit poisonous fumes. May emit corrosive fumes.

	May emit corrosive fumes.	
SECTION 6: ACCIDE	ENTAL RELEASE MEASURES	
6.1 Personal precautions, protective equipment and emergency procedures		
For information on pr	otective equipment, see section 8	
6.2 Environmental Precautions		
See sect	ion 12	
6.3 Methods and material for containment and cleaning up Spills are unlikely due to the nature of the product and how it is packaged		
Minor Spills:	Clean up all spills immediately. Avoid contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Use dry clean up procedures and avoid generating dust. Place in a suitable, labelled container for waste disposal.	
Major Spills:	Alert Emergency Services and tell them location and nature of hazard. Control personal contact by wearing protective clothing. Prevent, by any means available, spillage from entering drains or water courses.	

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SECTION 7: HANDLING AND STORAGE	
7.1 Precautions for safe h	andling
Safe Handling:	Wear suitable clothing when risk of exposure occurs. Do not eat, drink or smoke while handling the tablet or used litter. Wash hands with soap and water after handling litter used by treated animals. Observe manufacturer's storage and handling recommendations.
Other Information:	Store in original containers in a cool, dry area. Keep containers securely sealed. Do not break or crush tablets. Keep out of the reach and sight of children.
7.2 Conditions for safe sto	orage, including any incompatibilities
Suitable Container:	Keep the container tightly closed in order to protect from moisture. Tablets stored in a white polypropylene tub with white low density polyethylene tamper evident lid containing 100 tablets. Keep the container in the outer carton. Do not store above 25°C. Check all containers are clearly labelled and free from leaks. Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Storage incompatibility:	None known.
7.3 Specific end uses	
Not available	

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION
8.1 Control parameters
DERIVED NO EFFECT LEVEL - DNEL (EU)
Not Available
PREDICTED NO EFFECT LEVEL - PNEC (EU)
Not Available
OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA (EU):
Not Available

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NGREDIENT DATA (US):			
Not Available			
EMERGENCY LIMITS (EU/US):			
Not Available			
8.2 Exposure controls			
	The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the particular risk.		
Personal protection:			
Eye and face protection:	Safety glasses with side shields / chemical goggles		
Skin protection:	tection: See hand protection below		
Hands/ feet protection:	On: No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves. As thiamazole is a suspected human teratogen, pregnant women, and women of child-bearing age, should wear gloves when handling the product or the litter used by treated animals.		
Body protection:	Wear appropriate clothing		
Other protection:	No special equipment needed when handling small quantities		
Thermal hazards:	nazards: Not available		
Respiratory protection:	Respiratory protection: Not applicable		
8.3 Environmental exposure co See Section 12	ontrols		

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Active: A white or pale brown crystalline powder.

Tablet: Red sugar-coated biconvex tablets 5.5 mm diameter.

Container: White polypropylene tub with white low density polyethylene tamper evident lid

containing 100 tablets. **Physical state:** Solid

Odour: Faint characteristic odour **Odour Threshold:** Not available

pH (as supplied): Solutions in water are practically neutral to litmus

Melting point / freezing point (degrees C): 146°C -148°C

Initial boiling point and boiling range: 280°C (with some decomposition)

Flash Point: Not applicable Evaporation rate: Not available Flammability: Not available

Upper/lower flammability or explosive limits: Not available

Vapour pressure: Not available

Relative Density (at degrees C): Not available

Solubility in water and solvents (mg/l): Water: Soluble 1 in 5

Alcohol: Soluble 1 in 5 Chloroform: Soluble 1 in 4.5 Ether: Soluble 1 in 125

Vapour density: Not available

Auto ignition temperature (degrees C): Not available Decomposition temperature (degrees C): Not available

Viscosity: (degrees C): Not available Explosive properties: Not available Oxidising properties: Not available Partition Coefficient: Not available

Molecular weight: 114.17 Taste: Not available

Surface tension: Not available
Volative component: Not available

Gas group: Not available pH as a solution: Not available

VOC q/L: Not available

9.2 Other information

Not Available

10: REACTIVITY AND STABILITY		
10.1 Reactivity:	Avoid reaction with oxidizing agents.	
10.2 Chemical stability:	Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur.	
10.3 Possibility of	The product is not considered to be hazardous if used as per	

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hazardous reactions:	instructions. Will not polymerize.	
10.4 Conditions to avoid:	Avoid heat, flame and ignition sources. May emit toxic fumes under fire conditions.	
10.5 Incompatible materials:	Unstable in the presence of incompatible materials.	
10.6 Hazardous decomposition:	See Section 5.	

SECTION 11: TOXIC	COLOGICAL INFORMATION
Inhalation:	Not normally a hazard due to the nature of product. Material can however cause respiratory irritation in some persons. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.
Ingestion:	Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.
Skin contact:	Skin contact is not thought to produce harmful health effects. Open cuts, abraded or irritated skin should not be exposed to this material. Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects.
Eye contact:	Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result.
Chronic:	Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems. Strong evidence exists that this substance may cause irreversible mutations (though not lethal) even following a single exposure. Ample evidence from experiments exists that there is a suspicion this material directly reduces fertility. Based on experience with animal studies, exposure to the material may result in toxic effects to the development of the foetus, at levels which do not cause significant toxic effects to the mother. Laboratory (in vitro) and animal studies show, exposure to the material may result in a possible risk of irreversible effects, with the possibility of producing mutation. Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.

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SECTION 11: TOXICOLOGICAL INFORMATION		
Felimazole Coated Tablets 1.25mg, 2.5mg, 5mg:		Irritation
	Not Available	Not Available
	Acute toxicity	Irritation
Methimazole:	Oral (rat) LD ₅₀ : 2250 mg/kgd ¹	May cause skin and eye irritation.
1 * Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted		

^{1.*} Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances

Acute toxicity:

There have been few reports of overdose, although it is known that thiamazole may cause vomiting, epigastric distress, headache, fever, arthralgia, pruritis and pancytopaenia. Treatment of overdose is symptomatic and supportive as there is no antidote.

Skin corrosion/irritation:

Not expected to cause irritation.

Serious eye damage/ irritation:

Not expected to cause irritation.

Respiratory or skin sensitization:

Not expected to cause irritation.

Germ cell mutagenicity:

Laboratory (in vitro) and animal studies show, exposure to the material may result in a possible risk of irreversible effects, with the possibility of producing mutation.

Carcinogenicity:

Not Available

Reproductive toxicity:

Ample evidence from experiments exists that there is a suspicion this material directly reduces fertility.

Based on experience with animal studies, exposure to the material may result in toxic effects to the development of the foetus, at levels which do not cause significant toxic effects to the mother.

STOT - single exposure:

May cause respiratory irritation.

STOT-repeated exposure:

Not available

Aspiration hazard:

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SECTION 11: TOXICOLOGICAL INFORMATION

Not available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Felimazole Coated Tablets – 2.5mg, 5mg:	Endpoint	Test Duration (Hr)	Species	Value	Source
	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Thiamazole/	LC ₅₀	96	Fish	1274.195mg/L	3
Methimazole:	EC ₅₀	96	Algae or other aquatic plants	9061.206mg/L	3
	EC ₅₀	384	Crustacea	288.626mg/L	3
	NOEC	56dpf	Fish	0.1136mg/L	4

DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
Thiamazole/Methimazole	LOW	LOW

12.3 Bioaccumulative potential

Ingredient	Bioaccumulation
Thiamazole/Methimazole	LOW (LogKOW = -0.34)

12.4 Mobility in Soil

Ingredient	Mobility	
Thiamazole/Methimazole	LOW (KOC = 8.088)	

12.5 Results of PBT and vPvB assessment

Not Available

12.6 Other adverse effects

Not Available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product / DO NOT allow wash water from cleaning or process equipment to packaging enter drains.

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disposal:	Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.
	Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area.
	Recycle wherever possible or consult manufacturer for recycling options. Consult State Land Waste Management Authority for disposal.
	Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.
Waste Treatment Options:	
Sewage Disposal Options:	

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SECTION 14: TRANSPORT INFORMATION				
Labels required:				
Marine pollutant:	NO			
Hazchem:	Not Applicable			
Land transport (EU: DANGEROUS GOOD		GULATED FOR TRANSPORT OF		
14.1 UN Number	N/a			
14.2 UN Proper Shipping Name	N/a			
14.3 Transport	Class	N/a		
hazard class(es)	Sub risk	N/a		
14.4 Packing group	N/a			
14.5 Environmental hazards	N/a	N/a		
14.6 Special precautions for	Special provisions	N/a		
user	Limited quantity N/a			
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a			
Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS				
14.1 UN Number	N/a			
14.2 UN Proper Shipping Name	N/a			
14.3 Transport	ICAO/IATA Class	N/a		
hazard class(es)	ICAO / IATA Sub risk	N/a		
	ERG Code	N/a		
14.4 Packing group	N/a			
14.5 Environmental hazards	N/a			
-	Special provisions	N/a		
precautions for user	Cargo only packing instructions	N/a		

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	Cargo only maximun qty/pack	m N/a	
	Passenger and carg packaging instruction		
	Passenger and carg maximum qty/pack	o N/a	
	Passenger and carg limited quantity pack instructions		
	Passenger and carg limited maximum qty/pack	o N/a	
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a		
Sea transport (IMDG DANGEROUS GOOD		OT REGULATED FOR TRANSPORT OF	
14.1 UN Number	N/a		
14.2 UN Proper Shipping Name	N/a		
14.3 Transport	IMDG Class N/a		
hazard class(es)	IMDG Sub risk N/a		
14.4 Packing group	N/a		
14.5 Environmental hazards	N/a		
-	EMS Number	N/a	
precautions for user	Special provisions	N/a	
	Limited quantities	N/a	
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a		
Inland waterways tra DANGEROUS GOOD		REGULATED FOR TRANSPORT OF	

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14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	N/a N/a	
14.4 Packing group	N/a	
14.5 Environmental hazard	N/a	
	Classification Code	N/a
precautions for user	Special provisions	N/a
	Limited quantity	N/a
	Equipment required	N/a
	Fire cones number	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture

THIAMAZOLE / METHIMAZOLE (60-56-0) IS FOUND ON THE FOLLOWING REGULATORY LISTS:

- European Customs of Chemicals ECICS (English)
- European Union European inventory of existing chemical commodities (EINECS)
- International Agency for Cancer Research (IARC) Agents Issued by the IARC Monographs
- US International Agency for Research on Cancer (IARC) Agents Classified by the IARC Monographs
- US California Proposition 65 Reproductive Toxicity
- US Priority List for the Development of Proposition 65 Safe Harbour Levels No Significant Risk Levels (NSRLs) for Carcinogens and Maximum Allowable Dose Levels (MADLs) for Chemicals Causing Reproductive Toxicity
- US Toxic Substances Control Act (TSCA) Chemical Substance Inventory

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable: 98/24/EC, 92/85/EC, 94/33/EC, 91/689/EEC, 1999/13/EC

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15.2 Chemical Safety Assessment

60-56-0

ECHA SUMMARY

Thiamazole

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FEDERAL REGULATIONS:	
Superfund Amendments and Re	authorization Act of 1986 (SARA)
Section 311/312 Hazard Categor	ies
Immediate (acute) health hazard	Yes
Delayed (chronic) health hazard	Yes
Fire hazard	No
Pressure hazard	No
Reactivity hazard	No
US. EPA Cercla Hazardous Subs	stances and Reportable Quantities (40 CFR 302.4)
None Reported	
STATE REGULATIONS	
US. CALIFORNIA PROPOSITION	I 65
WARNING: This product contains cancer and birth defects or other re	a chemical known to the State of California to cause eproductive harm
US - CALIFORNIA PREPOSITION (CRT): LISTED SUBSTANCE	N 65 - CARCINOGENS & REPRODUCTIVE TOXICITY
Methimazole listed	

Ingredient	CAS number	Index Number	ECHA Dossier

Not Available

Not Available

Harmonization (C&L Inventory)		Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Skin Sens. 1, Repr. 2	GHS07, GHS08, Wng	H317, H361
2	Skin Sens. 1, Repr. 2, Acute Tox. 4	GHS08, Wng	H317, H361, H302, H332, H315, H335, H319

Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification

National Inventory	Status
Australia - AICS	Υ
Canada - DSL	Υ
Canada - NDSL	N (thiamazole/methimazole)

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China - IECSC	Υ
Europe - EINEC / ELINCS / NLP	Υ
Japan - ENCS	Υ
Korea - KECI	Υ
New Zealand - NZIoC	Υ
Philippines - PICCS	N (thiamazole/methimazole)
USA - TSCA	Υ
Legend:	Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

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SECTION 16: OTHER INFORMATION

The SDS is written in accordance to guidelines specified by REACH, GHS, OSHA and ECHA.

Full text Risk and Hazard codes:

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes severe eye irritation.
H332	Harmful if inhaled.
H361	May possibly harm the fertility of the unborn child.

Relevant risk statements are found in section 2.1

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

EN 166 - Personal eye protection

EN 340 - Protective clothing

EN 374 - Protective gloves against chemicals and microorganisms

EN 13832 - Protective footwear against chemicals

EN 133 - Respiratory protection

NFPA 704 diamond (US):



Blue = Health, Red = Fire, Yellow = Reactivity, White = Special (Oxidizer or water reactive substances)

Definitions and abbreviations

PC—TWA: Permissible Concentration-Time Weighted Average PC—STEL: Permissible Concentration-Short Term Exposure Limit

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit

IDLH: Immediately Dangerous to Life or Health Concentrations

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