

Methimazole Coated Tablets

Safety Data Sheet



Date of issue: 02 Jun 2025

Version:.00

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Name: Methimazole Coated Tablets 2.5 mg and 5 mg

1.2. Intended Use of the Product

Methimazole Coated Tablets (methimazole tablets) are indicated for the treatment of hyperthyroidism in cats.

1.3. Name, Address of the Responsible Party

Felix Pharmaceuticals Private Limited,
25-28 North Wall Quay Dublin 1, Ireland

1.4. Emergency Telephone Number

Emergency Number: Contact Felix Pharmaceuticals Private Limited at 1-833-571-1525.

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification (GHS-US)

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



2.3. Other Hazards

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

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Ingredient Name

Methimazole

3.2. Chemical Formula:

2H-imidazole-2-thione,1,3-dihydro-1-methyl
(OR)

1-Methylimidazole-2-thiol

3.3. Mixture

Component	Approximate Quantity	CAS number
Methimazole	2.5/5 mg	200-482-4
Non-hazardous Ingredients	q.s	Not Applicable

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: Wash hands with soap and water after handling litter used by treated animals.

First-aid Measures After 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.

First-aid Measures After 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.

First-aid Measures After 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.

First-aid Measures After Ingestion: IF SWALLOWED, SEEK MEDICAL ATTENTION WITHOUT DELAY. For advice, contact a Poisons Information Centre or a medical practitioner.

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4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries After Inhalation: Material can however cause respiratory irritation in some persons.

Symptoms/Injuries After Skin Contact: Open cuts, abraded or irritated skin should not be exposed to this material. It may produce systemic injury with harmful effects.

Symptoms/Injuries After Eye Contact: Direct contact with eyes may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn).

Symptoms/Injuries After Ingestion: Accidental ingestion of the material may be harmful.

Chronic Symptoms: Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems.

4.3. Indication of Any 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.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Select extinguishing media suitable for surrounding area.

Unsuitable Extinguishing Media: There is no restriction on the type of extinguisher which may be used.

5.2. Special Hazards Arising from the Substance or Mixture

Fire Hazard: Non-combustible.

Explosion Hazard: Not considered a significant fire risk, however containers may burn.

Reactivity: Avoid reaction with oxidizing agents.

Special Fire Fighting Procedure: Wear breathing apparatus plus protective gloves in the event of a fire.

5.3. Advice for Firefighters

Precautionary Measures Fire: Prevent, by any means available, spillage from entering drains or water courses.

Firefighting Instructions: Cool fire exposed containers with water spray from a protected location.

Protection During Firefighting: DO NOT approach containers suspected to be hot.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Use personal protective equipment while handling the material.

6.2. Environmental Precautions DO NOT discharge into sewer or waterways.

6.3. Methods and Material for Containment and Cleaning Up

Methods for Cleaning Up: Spills are unlikely due to the nature of the product and how it is packaged.

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.

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.

6.4. Reference to Other Sections

For waste disposal, see section 13 of the SDS, and for personal protection, see section 8 of the SDS.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Hygiene Measures: Wear suitable clothing when risk of exposure occurs.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F) [see USP Controlled Room Temperature].

Incompatible Products: None known.

7.3. Specific End Use(s)

No data available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

No data available.

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8.2. Exposure Controls

- Appropriate Engineering 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 Protective Equipment : Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
- Hand Protection : Wear chemical protective gloves.
- Eye Protection : If contact is likely, safety glasses with side shields/ chemical goggles are recommended.
- Skin and Body Protection : Wear chemical protective gloves.
- Respiratory Protection : Not applicable.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

- Physical State** : Solid
- Appearance** : 2.5 mg: Light pink to pink color, round shaped, sugar-coated biconvex tablets.
5 mg: Light orange to orange color, round shaped, sugar-coated biconvex tablets.
- Odor** : No data available
- Odor Threshold** : No data available
- pH** : No data available
- Evaporation Rate** : No data available
- Melting Point** : No data available
- Freezing Point** : No data available
- Boiling Point** : No data available
- Flash Point** : No data available
- Auto-ignition Temperature** : No data available
- Decomposition Temperature** : No data available
- Flammability (solid, gas)** : No data available
- Vapor Pressure** : No data available
- Relative Vapor Density at 20 °C** : No data available
- Relative Density** : No data available
- Solubility** : No data available
- Partition Coefficient: N-Octanol/Water** : No data available
- Viscosity** : No data available

9.2. Other Information: No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity : Avoid reaction with oxidizing agents.
- 10.2. Chemical Stability : Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerization will not occur.
- 10.3. Possibility of Hazardous Reactions : The product is not considered to be hazardous if used as per 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 Products : Decomposition may produce toxic fumes of: Sulphur oxides (SO_x).

SECTION 11: TOXICOLOGICAL INFORMATION

- 11.1. Acute Toxicity : There have been few reports of overdose, although it is known that methimazole may cause vomiting, epigastric distress, headache, fever, arthralgia, pruritis and pancytopenia. Treatment of overdose is symptomatic and supportive as there is no antidote.

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- 11.2.** Local Effects : Not Classified
- 11.3.** Reproductive Effects : 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
- 11.4.** 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.

SECTION 12: ECOLOGICAL INFORMATION

- 12.1.** Toxicity : No additional information available.
- 12.2.** Persistence and Degradability : No additional information available.
- 12.3.** Bio accumulative Potential : No additional information available
- 12.4.** Mobility in Soil : No additional information available
- 12.5.** Other Adverse Effects : No other adverse environmental effects

SECTION 13: DISPOSAL CONSIDERATIONS

- 13.1. Waste treatment methods**
- Waste Disposal Recommendations** : DO NOT allow wash water from cleaning or process equipment to enter drains. 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.

SECTION 14: TRANSPORT INFORMATION

- 14.1.** Transport according to all local, state and federal regulation

SECTION 15: REGULATORY INFORMATION

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

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

- 16.1. Previous Version** : **Effective Date**
- Nil : Nil

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product. To the best of Felix's knowledge, the information contained here is accurate. However, neither the above-named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All material may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist