

Maropitant Citrate Tablets

Safety Data Sheet



Date of issue: 06 May 2024

Version:.00

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Name: Maropitant Citrate Tablets 16, 24, 60 and 160 mg

1.2. Intended Use of the Product

Use of the substance/mixture: Maropitant Citrate tablets are indicated for the prevention of acute vomiting and the prevention of vomiting due to motion sickness in dogs.

1.3. Name, Address of the Responsible Party

Felix Pharmaceuticals Private Limited
25-28, North Wall Quay, D01H104,
Dublin 1, Republic of 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)

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). It is in solid, final form for direct administration to the patient. Therefore, it is exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(6)(vii).

2.2. Label Elements

Physical hazard is not classified. However, it is serious hazards for eye damage/eye irritation, Specific target organ toxicity, Hazardous to the aquatic environment, Signal word is danger.

2.3. Other Hazards

Causes serious eye damage. May cause damage to organs (cardiovascular system, liver) through prolonged or repeated exposure. Toxic to aquatic life with long lasting effects.

2.4. Unknown Acute Toxicity (GHS-US)

Individuals with cardiac conditions may be more susceptible to toxicity in cases of overexposure.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Ingredient Name

Maropitant citrate monohydrate

3.2. Chemical Formula: $C_{32}H_{40}N_2O \cdot C_6H_8O_7 \cdot H_2O$

3.3. Mixture

Component	Approximate Quantity	CAS number
Maropitant citrate monohydrate	16/24/60/160 mg	359875-09-5
Non-hazardous Ingredients	q.s	Not Applicable

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: If you feel unwell, seek medical advice.

First-aid Measures After Inhalation: Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.

First-aid Measures After Skin Contact: Wash off with soap and plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse.

First-aid Measures After Eye Contact: Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately.

First-aid Measures After Ingestion: Rinse mouth. Call a physician or poison control center immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.

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

Symptoms/Injuries After Inhalation: Prolonged inhalation may be harmful.

Symptoms/Injuries After Skin Contact: Prolonged skin contact may cause temporary irritation.

Symptoms/Injuries After Eye Contact: Causes serious eye damage.

Chronic Symptoms: May cause damage to organs through prolonged or repeated exposure.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

Maropitant Citrate Tablets

Safety Data Sheet



SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).

Unsuitable Extinguishing Media: Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special Hazards Arising from the Substance or Mixture

Fire Hazard: No unusual fire hazards noted.

Explosion Hazard: No explosion hazards noted.

Reactivity: The product is stable and non-reactive under normal conditions of use, storage and transport.

Special Fire Fighting Procedure: Use standard firefighting procedures and consider the hazards of other involved materials. Self-contained breathing apparatus and full protective clothing must be worn in case of fire. Use water spray to cool unopened containers.

5.3. Advice for Firefighters

Precautionary Measures Fire: Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Firefighting Instructions: Use water spray for cooling exposed containers.

Protection During Firefighting: Wear appropriate protective equipment and clothing during clean-up. Do not breathe dust. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure. Ensure adequate ventilation. Avoid dust formation. Ventilate the contaminated area.

6.2. Environmental Precautions:

Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

6.4. Reference to Other Sections

See Heading 8. Exposure controls and personal protection. For further information refer to section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Hygiene Measures: Use with adequate ventilation. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Avoid contact with eyes, skin, and clothing. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Avoid prolonged exposure. Wash hands thoroughly after handling. When using, do not eat, drink or smoke. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Avoid release to the environment.

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 (between 59° and 86°F). [see USP controlled room temperature].

Incompatible Products: Strong oxidizing agents. Fluorine.

7.3. Specific End Use(s)

Antiemetic

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

8.2. Exposure Controls

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. General ventilation normally adequate. Provide eyewash station

Maropitant Citrate Tablets

Safety Data Sheet



Personal Protective Equipment	: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hand Protection	: Wear protective gloves. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eye Protection	: Wear protective gloves. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Skin and Body Protection	: Wear suitable protective clothing. Use protective clothing (uniforms, lab coats disposable coveralls, etc.) in both production and laboratory areas
Respiratory Protection	: No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Solid
Appearance	: Light peach to orange mottle-colored oval 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:** The product is stable and non-reactive under normal conditions of use, storage and transport.
- 10.2. Chemical Stability:** Material is stable under normal conditions.
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization does not occur.
- 10.4. Conditions to Avoid:** Contact with incompatible materials. Heat, flames and sparks. High temperatures. Sunlight.
- 10.5. Incompatible Materials:** Strong oxidizing agents. Fluorine.
- 10.6. Hazardous Decomposition Products:** Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

SECTION 11: TOXICOLOGICAL INFORMATION

Local Effects:	Not Classified.
Reproductive Effects:	Negative.
Mutagenicity:	Negative.

SECTION 12: ECOLOGICAL INFORMATION

- 12.1. Toxicity:** Toxic to aquatic life with long lasting effects. Avoid release to the environment.
- 12.2. Persistence and Degradability:** No data is available on the degradability of this product. In the environment, the active ingredient in this formulation is expected to degrade slowly.
- 12.3. Bio accumulative Potential:**

Partition coefficient n-octanol / water (log Kow)	
Maropitant citrate monohydrate	5.12, (+/- 0.01)

Maropitant Citrate Tablets

Safety Data Sheet



12.4. Mobility in Soil:

Adsorption Soil/sediment sorption - log Koc

Maropitant citrate monohydrate

4.16, (estimated)

12.5. Other Adverse Effects No other adverse environmental effects.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Avoid release to the environment. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and waste water. Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: TRANSPORT INFORMATION

Transport according to all local, state and federal regulation

SECTION 15: REGULATORY INFORMATION

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

Revision Date : Not Applicable

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.