

SAFETY DATA SHEET

Product Name: Maropitant Citrate Tablets

Strength : 16, 24, 60 and 160 mg

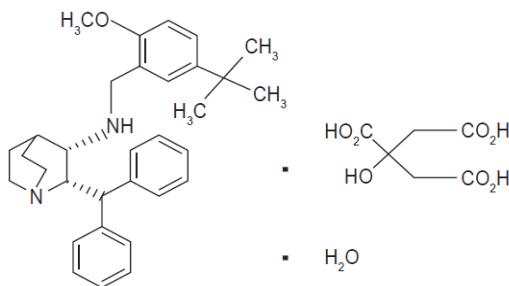
Revision No.: 00

Emergency Overview

Keep unnecessary personnel away. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Ensure adequate ventilation. Avoid dust formation. Ventilate the contaminated area. 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. For personal protection, see section 8 of the SDS.

Section 1: Identification

Product Name: Maropitant Citrate Tablets
Formula: C₃₂H₄₀N₂O C₆H₈O₇ H₂O
Chemical Name: (2*S*,3*S*)-2-benzhydryl-*N*-(5-*tert*-butyl-2-methoxybenzyl) quinuclidin-3-amine citrate monohydrate



Molecular Weight: 678.81.

Description : Maropitant is a neurokinin (NK1) receptor antagonist that blocks the pharmacological action of substance P in the central nervous system (CNS). Maropitant is the non-proprietary designation for a substituted quinuclidine. The empirical formula is C₃₂H₄₀N₂O C₆H₈O₇ H₂O and the molecular weight 678.81. The chemical name is (2*S*,3*S*)-2-benzhydryl-*N*-(5-*tert*-butyl-2-methoxybenzyl) quinuclidin-3-amine citrate monohydrate. Each peach-colored oval tablet is scored and contains 16, 24, 60 or 160 mg of maropitant as maropitant citrate per tablet.

Product Name	Strength	Pack count	NDC
Maropitant Citrate Tablets	16 mg	Blister pack of 4 tablets	8611702717
	24 mg	Blister pack of 4 tablets	8611702817
	60 mg	Blister pack of 4 tablets	8611702917
	160 mg	Blister pack of 4 tablets	8611703017

Manufacturer / supplier identification

Company Zydus Animal Health and Investments Limited,
Ahmedabad, India
Contact for information Tel.: +91 2717-683954
Emergency Telephone No Tel.: +91 2717-683951
Distributed by: ZyVet Animal Health Inc.
Pennington, NJ 08534

Section 2: Hazard (s) Identification

Physical hazards Not classified.
Not classified.

Health hazards

Serious eye damage/eye irritation
Specific target organ toxicity, repeated exposure

Category 1
Category 2 (cardiovascular system, liver)

Environmental hazards

Hazardous to the aquatic environment, acute hazard
Hazardous to the aquatic environment, long-term hazard

Category 2
Category 2

OSHA defined hazards

Not classified.

Label elements



Signal word

Danger

Hazard statement

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.

Precautionary statement

Prevention

Do not breathe dust/fume/gas/mist/vapors/spray. Avoid release to the environment. Wear eye protection/face protection.

Response	Get medical advice/attention if you feel unwell. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor. Collect spillage.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Drugs of this class have been associated with rare, but potentially serious cardiac events. These effects have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

Section 3: Composition / information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Microcrystalline cellulose		9004-34-6	50 - 60
Maropitant citrate monohydrate		359875-09-5	23.2
Magnesium stearate		557-04-0	< 3

Composition comments In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.
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.
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.
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.
Most important symptoms/effects, acute and delayed	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Prolonged exposure may cause chronic effects. Individuals with cardiac conditions may be more susceptible to toxicity in cases of overexposure.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
General information	For personal protection, see section 8 of the SDS. IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

Section 5: Fire-fighting measures

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

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Ensure adequate ventilation. Avoid dust formation. Ventilate the contaminated area. 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.

Methods and materials for containment and cleaning up

For waste disposal, see section 13 of the SDS. Ensure adequate ventilation. Avoid dust formation. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Ground/bond container and equipment. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean contaminated surface thoroughly. Prevent release to the environment.

Small Spills: Wipe up with a damp cloth and place in container for disposal. Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use.

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.

Section 7: Handling & storage

Precautions for safe handling

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.

Conditions for safe storage, including any incompatibilities

Store in original tightly closed container. Store in a well-ventilated place. @ 15-30°C (59-86°F).. Keep away from heat, sparks and open flame.

Section 8 :Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Zoetis

Components	Type	Value
Maropitant citrate monohydrate (CAS 359875-09-5)	TWA	20 µg/m ³

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	PEL	5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	TWA	5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Magnesium stearate (CAS 557-04-0)	TWA	3 mg/m ³	Respirable fraction.
		10 mg/m ³	Inhalable fraction.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m ³	

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	TWA	5 mg/m ³	Respirable.
		10 mg/m ³	Total

Biological limit values	No biological exposure limits noted for the ingredient(s).
Control banding approach	Not available.
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.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Wear safety glasses or goggles if eye contact is possible. Chemical goggles are recommended.
Skin protection	
Hand protection	Wear protective gloves. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Other	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. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn.
Thermal hazards	Not applicable.
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.

Section 9: Physical and chemical properties

Appearance	Tablet
Physical state	Solid.
Form	Solid.
Color	Peach
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not 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	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

Section 10: Stability & reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials. Heat, flames and sparks. High temperatures. Sunlight.
Incompatible materials	Strong oxidizing agents. Fluorine.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

Section 11: Toxicological information

Information on likely routes of exposure

Inhalation	Prolonged inhalation may be harmful.	
Skin contact	Prolonged skin contact may cause temporary irritation.	
Maropitant citrate monohydrate		Species: Rabbit Severity: Non-irritating
Microcrystalline cellulose		Species: Rabbit Severity: Non-irritating
Eye contact	Causes serious eye damage.	
Microcrystalline cellulose		Species: Rabbit Severity: Non-irritating
Maropitant citrate monohydrate		Species: Rabbit Severity: Severe

Ingestion May cause discomfort if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Prolonged exposure may cause chronic effects.

Information on toxicological effects

Acute toxicity Not acutely toxic

Components	Species	Test Results
Magnesium stearate (CAS 557-04-0)		
Acute		
Inhalation		
LC50	Rat	> 2000 mg/m3
Oral		
LD50	Rat	> 2000 mg/kg
Maropitant citrate monohydrate (CAS 359875-09-5)		
Acute		
Dermal		
LD50	Rat	> 2000 mg/kg

Components	Species	Test Results
Oral LDmin.	Rat	1000 mg/kg (Maropitant methanesulfonate salt)
<u>Subchronic</u>		
Oral NOAEL	Dog	5 mg/kg/day, 3 months [Target organ(s): Cardiovascular system (Maropitant methanesulfonate salt)]
	Rat	5 mg/kg/day, 3 months [Target organ(s): Liver (Maropitant methanesulfonate salt)]
Microcrystalline cellulose (CAS 9004-34-6)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 5000 mg/kg
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Corrosivity		
Maropitant citrate monohydrate	Species: Rabbit	Severity: Non-irritating
Serious eye damage/eye irritation	Causes serious eye damage.	
Eye Contact		
Microcrystalline cellulose	Species: Rabbit	Severity: Non-irritating
Maropitant citrate monohydrate	Species: Rabbit	Severity: Severe
Respiratory or skin sensitization		
Respiratory sensitization	Not a respiratory sensitizer.	
Skin sensitization	This product is not expected to cause skin sensitization.	
Skin sensitization		
Maropitant citrate monohydrate	GPMT	Species: Guinea Pig Severity: Negative
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Mutagenicity		
Maropitant citrate monohydrate	Result: Negative (In vitro, in vivo - Maropitant methanesulfonate salt)	
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not listed.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)		
Not listed.		
US. National Toxicology Program (NTP) Report on Carcinogens		
Not listed.		
Reproductive toxicity	This product is not expected to cause reproductive or developmental effects. Based on available data, the classification criteria are not met.	

Developmental effects

Maropitant citrate monohydrate

150 mg/kg/day Embryo / Fetal Development, Not teratogenic
Result: NOEL
Species: Rat

Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	May cause damage to organs (cardiovascular system, liver) through prolonged or repeated exposure.
Aspiration hazard	Not an aspiration hazard.
Chronic effects	May cause damage to organs through prolonged or repeated exposure. Prolonged inhalation may be harmful.
Further information	Drugs of this class have been associated with rare, but potentially serious cardiac events. These effects have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

Section 12: Ecological information

Ecotoxicity Toxic to aquatic life with long lasting effects. Avoid release to the environment.

Components	Species	Test Results	
Maropitant citrate monohydrate (CAS 359875-09-5)			
Aquatic			
	IC50	Red Algae	0.23 mg/l, 7 days
	NOEC	Red Algae	0.082 mg/l, 7 days
Crustacea	EC50	Daphnia magna (Water Flea)	0.6 mg/l, 1.25 hours
	LC50	Mysidopsis bahia (Mysid Shrimp)	0.68 mg/l, 48 hours
	NOEC	Daphnia magna (Water Flea)	0.31 mg/l, 1.25 hours
		Mysidopsis bahia (Mysid Shrimp)	0.302 mg/l, 48 hours
Fish	LC50	Cyprinodon variegatus (Sheepshead Minnow)	0.68 mg/l, 48 hours
	NOEC	Cyprinodon variegatus (Sheepshead Minnow)	0.302 mg/l, 48 hours

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.

Bioaccumulative potential See below

Partition coefficient n-octanol / water (log Kow)

Maropitant citrate monohydrate 5.12, (+/- 0.01)

Mobility in soil No data available.

Adsorption**Soil/sediment sorption - log Koc**

Maropitant citrate monohydrate 4.16, (estimated)

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

Section 13: Disposal considerations

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

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code None known.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner.

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

Section 14: Transport information**DOT**

Not regulated as dangerous goods.

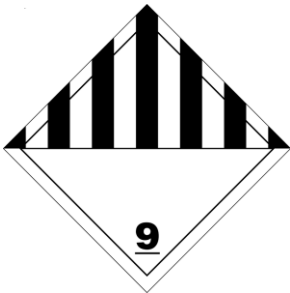
IATA

UN number	UN3077
UN proper shipping name	Environmentally Hazardous Substance, Solid, n.o.s (Maropitant citrate monohydrate)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	Yes
Special precautions for user	Not available.

IMDG

UN number	UN3077
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Maropitant citrate monohydrate), MARINE POLLUTANT (Maropitant citrate monohydrate)
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 applicable.

IATA; IMDG**Marine pollutant****General information**

IMDG Regulated Marine Pollutant. As of January 1, 2015, materials offered for transport that are classified for transportation only as Marine Pollutants and which are packaged in single or combination packagings containing a net quantity per single or inner packaging of 5 Liters or less for liquids or having a net mass per single or inner packaging of 5 kilograms or less for solids are NOT subject to ICAO/IATA, IMDG, or ADR transport regulations provided the general packaging requirements of those regulations are met. Refer to ICAO/IATA A197, IMDG 2.10.2.7, ADR SP 375. Please refer to the applicable dangerous goods regulations for additional information. Transport according to the requirements of the appropriate regulatory body.

Section15: 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 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**SARA 302 Extremely hazardous substance**

Not listed.

SARA 311/312 Hazardous chemical

Yes

Classified hazard categories

Serious eye damage or eye irritation
Specific target organ toxicity (single or repeated exposure)

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.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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).

Section16: Other information, including date of preparation or last revision

Issue date 25-01-2023

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product