SAFETY DATA SHEETS

This SDS packet was issued with item: 078952217

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078952186 078952187 078952188 078952189 078952218 078952219 078952220

SAFETY DATA SHEET

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

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: Formula: Chemical Name: Maropitant Citrate Tablets C32H40N2O C6H8O7 H2O (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 (2S,3S)-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

Contact for information Emergency Telephone No Distributed by: Zydus Animal Health and Investments Limited, Ahmedabad, India Tel.: +91 2717-683954

Tel.: +91 2717-683951 ZyVet Animal Health Inc. Pennington, NJ 08534

Physical hazards Not classified. Not classified. Category 1 Health hazards Serious eye damage/eye irritation Category 2 (cardiovascular system, liver) Specific target organ toxicity, repeated exposure Category 2 **Environmental hazards** Hazardous to the aquatic environment, acute hazard Category 2 Hazardous to the aquatic environment, long-term hazard Not classified. **OSHA** defined hazards Label elements Signal word Danger Hazard statement Causes serious eye damage. May cause damage to organs (cardiovascular system, liver) through

protection/face protection.

Precautionary statement

Prevention

prolonged or repeated exposure. Toxic to aquatic life with long lasting effects.

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

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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

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 exwithheld as a trade secret.	xact percentage composition o	f this mixture has been
Section 4: First-aid measures			
Inhalation	Move to fresh air. Call a physician if symptom may be necessary.	s develop or persist. For breat	hing difficulties, oxygen
Skin contact	Wash off with soap and plenty of water. If skir off contaminated clothing and wash before re		advice/attention. Take
Eye contact	Immediately flush eyes with plenty of water for present and easy to do. Continue rinsing. Get		
Ingestion	Rinse mouth. Call a physician or poison cont advice from poison control center. Never give is having convulsions.		
Most important symptoms/effects, acute and delayed	Severe eye irritation. Symptoms may include vision. Permanent eye damage including blin chronic effects. Individuals with cardiac condi overexposure.	dness could result. Prolonged	exposure may cause
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and tre Symptoms may be delayed.	at symptomatically. Keep victir	n under observation.
General information	For personal protection, see section 8 of the s advice/attention. Ensure that medical person precautions to protect themselves.		
Section 5:Fire-fighting measures			
Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carb	on dioxide (CO2).	
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as th		
Specific hazards arising from the chemical	During fire, gases hazardous to health may b	e formed.	
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full p	rotective clothing must be worr	n in case of fire.
Fire fighting equipment/instructions	Use water spray to cool unopened containers	i.	
Specific methods General fire hazards	Use standard firefighting procedures and con No unusual fire or explosion hazards noted.	sider the hazards of other invo	lved materials.

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	Туре	Value	
Maropitant citrate monohydrate (CAS 359875-09-5)	TWA	20 µg/m³	
US. OSHA Table Z-1 Limits for Air	Contaminants (29 CFR 1910.1000)		
Components	Туре	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
US. OSHA Table Z-3 (29 CFR 1910	.1000)		
Components	Туре	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	TWA	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.
US. ACGIH Threshold Limit Value	S		
Components	Туре	Value	Form
Magnesium stearate (CAS 557-04-0)	TWA	3 mg/m3	Respirable fraction.
		10 mg/m3	Inhalable fraction.

US. ACGIH Threshold Limi Components	t Values Type	Value	Form	
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m3		
US. NIOSH: Pocket Guide t Components	o Chemical Hazards Type	Value	Form	
Microcrystalline cellulose (CAS 9004-34-6)	TWA	5 mg/m3	Respirable.	
		10 mg/m3	Total	
Biological limit values	No biological exposure limits noted for th	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.		res, local exhaust ventilation, nmended exposure limits. If	
Individual protection measures Eye/face protection	s, such as personal protective equipment Wear safety glasses or goggles if eye co	ntact is possible. Chemical	goggles are recommended.	
Skin protection Hand protection	Wear protective gloves. Impervious glove possible and for bulk processing operation		contact with drug product is	
Other	Wear suitable protective clothing. Use pr coveralls, etc.) in both production and lab		lab coats, disposable	
Respiratory protection	No personal respiratory protective equipr wear suitable respiratory equipment. Res exposure to dust, mists, aerosols or vapo airborne concentrations below recomment acceptable level (in countries where expo respirator must be worn. Not applicable.	spiratory protection should bors are likely. If engineering inded exposure limits (where	be provided in instances where controls do not maintain e applicable) or to an	
		noncurae, cuch ac weeking	after handling the material	
General hygiene considerations	Always observe good personal hygiene r and before eating, drinking, and/or smoki 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.
рН	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 expl	osive 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 norma	
Possibility of hazardous reactions	Hazardous polymerization doe	es not occur.
Conditions to avoid	Contact with incompatible mat	erials. Heat, flames and sparks. High temperatures. Sunlight.
Incompatible materials	Strong oxidizing agents. Fluor	ine.
Hazardous decomposition products	Irritating and/or toxic fumes ar	nd gases may be emitted upon the product's decomposition.
Section 11: Toxicological information	tion	
Information on likely routes of ex	xposure	
Inhalation	Prolonged inhalation may be l	narmful.
Skin contact	Prolonged skin contact may ca	ause temporary irritation.
Maropitant citrate monohydrat	e	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 monohydrat	e	Species: Rabbit Severity: Severe
Ingestion	May cause discomfort if swallo	owed.
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 effe	ects	
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 (C	AS 359875-09-5)	
Acute		
Dermal	Det	0000 "
LD50	Rat	> 2000 mg/kg

	Species	Test Results
Oral	_	
LDmin.	Rat	1000 mg/kg (Maropitant methanesulfonate salt)
Subchronic		
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)	
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 5000 mg/kg
Skin corrosion/irritation	Prolonged skin contact i	may cause temporary irritation.
Corrosivity		
Maropitant citrate r	nonohydrate	Species: Rabbit Severity: Non-irritating
Serious eye damage/eye rritation	Causes serious eye dan	nage.
Eye Contact		
Microcrystalline ce	llulose	Species: Rabbit Severity: Non-irritating
Maropitant citrate r	nonohydrate	Species: Rabbit Severity: Severe
Respiratory or skin sensitization	on	
Acophatory of Skill Scholazati		701
Respiratory sensitization	Not a respiratory sensitizer.	
Respiratory sensitization	This product is not over	
Skin sensitization	This product is not expe	cted to cause skin sensitization.
Skin sensitization Skin sensitization Maropitant citrate i	monohydrate	cted to cause skin sensitization. GPMT Species: Guinea Pig Severity: Negative cate product or any components present at greater than 0.1% are
Skin sensitization Skin sensitization Maropitant citrate i Germ cell mutagenicity	monohydrate No data available to indi	cted to cause skin sensitization. GPMT Species: Guinea Pig Severity: Negative cate product or any components present at greater than 0.1% are
Skin sensitization Skin sensitization Maropitant citrate i	nonohydrate No data available to indi mutagenic or genotoxic.	cted to cause skin sensitization. GPMT Species: Guinea Pig Severity: Negative cate product or any components present at greater than 0.1% are
Skin sensitization Skin sensitization Maropitant citrate n Germ cell mutagenicity Mutagenicity Maropitant citrate n	monohydrate No data available to indi mutagenic or genotoxic. nonohydrate	cted to cause skin sensitization. GPMT Species: Guinea Pig Severity: Negative cate product or any components present at greater than 0.1% are Result: Negative (In vitro, in vivo - Maropitant
Skin sensitization Skin sensitization Maropitant citrate n Germ cell mutagenicity Mutagenicity Maropitant citrate n Carcinogenicity	monohydrate No data available to indi mutagenic or genotoxic. nonohydrate	cted to cause skin sensitization. GPMT Species: Guinea Pig Severity: Negative cate product or any components present at greater than 0.1% are Result: Negative (In vitro, in vivo - Maropitant methanesulfonate salt) idered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
Skin sensitization Skin sensitization Maropitant citrate i Germ cell mutagenicity Mutagenicity Maropitant citrate i Carcinogenicity IARC Monographs. Overa Not listed. OSHA Specifically Regula	nonohydrate No data available to indi mutagenic or genotoxic. nonohydrate This product is not cons	cted to cause skin sensitization. GPMT Species: Guinea Pig Severity: Negative cate product or any components present at greater than 0.1% are Result: Negative (In vitro, in vivo - Maropitant methanesulfonate salt) idered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. hicity
Skin sensitization Skin sensitization Maropitant citrate i Germ cell mutagenicity Mutagenicity Maropitant citrate i Carcinogenicity IARC Monographs. Overa Not listed. OSHA Specifically Regula Not listed.	monohydrate No data available to indi mutagenic or genotoxic. nonohydrate This product is not cons Il Evaluation of Carcinoger	cted to cause skin sensitization. GPMT Species: Guinea Pig Severity: Negative cate product or any components present at greater than 0.1% are Result: Negative (In vitro, in vivo - Maropitant methanesulfonate salt) idered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. hicity 910.1001-1053)

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 cadiovascular illnesses may be at increased risk from exposure.

Section12: Ecological information

Ecotoxicity Toxic to aquatic life with long lasting effects. Avoid release to the environment. **Test Results** Components **Species** Maropitant citrate monohydrate (CAS 359875-09-5) Aquatic IC50 **Red Algae** 0.23 mg/l, 7 days Red Algae NOEC 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 0.68 mg/l, 48 hours Minnow) NOEC Cyprinodon variegatus (Sheepshead 0.302 mg/l, 48 hours Minnow) No data is available on the degradability of this product. In the environment, the active ingredient in Persistence and degradability this formulation is expected to degrade slowly. **Bioaccumulative potential** See below Partition coefficient n-octanol / water (log Kow) 5.12, (+/- 0.01) Maropitant citrate monohydrate 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 Avoid release to the environment. Considering the relevant known environmental and human **Disposal instructions** 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. Dispose in accordance with all applicable regulations. Local disposal regulations Hazardous waste code None known. Dispose of in accordance with local regulations. Empty containers or liners may retain some Waste from residues / unused product residues. This material and its container must be disposed of in a safe manner. products

Contaminated packaging

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

Section14: Transport information

DOT

Not regulated as dangerous goods.

IATA

IAIA	
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	
Environmental hazards	
Marine pollutant	Yes
EmS	F-A, S-F
Special precautions for user	Not available.
Transport in bulk according to	Not applicable.
Annex II of MARPOL 73/78 and	
the IBC Code	

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 Ha	
	Standard, 29 CFR 1910.1200.	zard Communication
Toxic Substances Control A	Act (TSCA)	
TSCA Section 12(b) Exp	port Notification (40 CFR 707, Subpt. D)	
Not regulated.		
CERCLA Hazardous Substa	nce List (40 CFR 302.4)	
Not listed.		
SARA 304 Emergency relea	se notification	
Not regulated. OSHA Specifically Regulate	d Substances (29 CFR 1910.1001-1053)	
Not listed.		
SARA 302 Extremely hazard	eauthorization Act of 1986 (SARA) dous 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 (I is not known to contain any chemicals currently listed as carcinogeneration of the second secon	
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
	Philippine Inventory of Chemicals and Chemical Substances	No
Philippines	(PICCS)	
Philippines Taiwan		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