SAFETY DATA SHEET

Section 1: Identification

Product identifier **Cerenia Tablets**

Other means of identification

Synonyms CERENIA * Cerenia® Tablets * Cerenia (maropitant citrate) Tablets * Cerenia® Tablets for Dogs * Maropitant Citrate Tablets

Recommended use of the chemical and restrictions on use

Recommended use Veterinary product used as Anti-emetic

Restrictions on use Not for human use

Details of manufacturer or importer

Company Name (NZ) Zoetis New Zealand Limited
Level 4, 8 Mahuhu Crescent
Auckland Central
Auckland 1010, New Zealand

Telephone No. 0800 963 847 (Business Hours)

Emergency No. (National Poisons Centre) 0800 POISON (0800 764 766)

Emergency No. (Emergency Services) In an emergency dial 111

Section 2: Hazard identification

Classification of the hazardous chemical

Physical hazards	Not classified.	
Health hazards	Serious eye damage/eye irritation	Category 1
	Specific target organ toxicity following repeated exposure	Category 2 (cardiovascular system, liver)
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 2
	Hazardous to the aquatic environment, long-term hazard	Category 2

Label elements, including precautionary statements

Hazard symbol(s)

Corrosion | Health hazard | Environment

Signal word Danger

Hazard statement(s) 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(s)

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

Response 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 CENTRE/doctor. Collect spillage.

Storage Store away from incompatible materials.

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

Other hazards which do not result in classification None.

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

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
Microcrystalline cellulose	9004-34-6	50 - 60
Maropitant citrate monohydrate	359875-09-5	23.2
Magnesium stearate	557-04-0	< 3

Section 4: First-aid measures

Description of necessary first aid measures

Inhalation Move to fresh air. For breathing difficulties, oxygen may be necessary. Call a physician if symptoms develop or persist.

Skin contact Wash off with soap and plenty of water. Take off contaminated clothing and wash before reuse. If skin irritation occurs: Get medical advice/attention.

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 Call a physician or poison control centre immediately. Rinse mouth. Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not induce vomiting without advice from poison control center.

Personal protection for first-aid responders 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. Wash contaminated clothing before reuse. For personal protection, see section 8 of the SDS. You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call.

Symptoms caused by exposure 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.

Medical attention and special treatment Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

Section 5: Fire-fighting measures

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.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for fire fighters 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.

Hazchem code None.

Hazards from combustion products None.

General fire hazards No unusual fire or explosion hazards noted.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away.

For emergency responders Wear appropriate protective equipment and clothing during clean-up. Ventilate the contaminated area. Keep unnecessary personnel away. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Ensure adequate ventilation. Do not breathe dust. Avoid dust formation. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid contact with eyes, skin, and clothing. Local authorities should be advised if significant spillages cannot be contained. Use personal protection recommended in Section 8 of the SDS.

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.

Methods and materials for containment and cleaning up Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Ground/bond container and equipment. Avoid dust formation. Ensure adequate ventilation. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean contaminated surface thoroughly.

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. For waste disposal, see section 13 of the SDS. Prevent release to the environment.

Section 7: Handling and storage

Precautions for safe handling 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. Avoid prolonged exposure. When using, do not eat, drink or smoke. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices. Use with adequate ventilation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

Conditions for safe storage, including any incompatibilities Store at 15-30°C (59-86°F). Keep away from heat, sparks and open flame. Store in a well-ventilated place. Keep away from food, drink and animal feeding stuffs. Store away from incompatible materials (see Section 10 of the SDS).

Section 8: Exposure controls/personal protection

Control parameters Follow standard monitoring procedures.

Occupational exposure limits

Zoetis

Components	Type	Value
Maropitant citrate monohydrate (CAS 359875-09-5)	TWA	20 µg/m³

New Zealand. OELs (Workplace Exposure Standards and Biological Exposure Indices)

Components	Type	Value	Form
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m3	
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m3	Fiber.

US. ACGIH Threshold Limit Values (TLV)

Components	Type	Value	Form
Magnesium stearate (CAS 557-04-0)	TWA	3 mg/m3	Respirable fraction.
		10 mg/m3	Inhalable fraction.
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m3	

UK. OELs. Workplace Exposure Limits (WELs) (EH40/2005 (Fourth Edition 2020)), Table 1

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	STEL	20 mg/m3	Inhalable dust.
	TWA	4 mg/m3	Respirable dust.
		10 mg/m3	Inhalable dust.

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value	Form
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m3	Inhalable dust.
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m3	Inhalable fibers.

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, for example personal protective equipment (PPE)

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. 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. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely.

Thermal hazards Not applicable.

Hygiene measures 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.

Colour Peach

Odour Not available.

Odour 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.

Vapour pressure Not available.

Vapour 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.
Kinematic viscosity	Not available.

Other physical and chemical parameters

Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

Section 10: Stability and 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	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Sunlight. Heat, flames and sparks. High temperatures. Contact with incompatible materials.
Incompatible materials	Strong oxidising 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
Oral		
LDmin.	Rat	1000 mg/kg (Maropitant methanesulfonate salt)

Components	Species	Test Results
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 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 irritation Not available.

Respiratory or skin sensitisation

Respiratory sensitisation Not a respiratory sensitiser.

Skin sensitisation This product is not expected to cause skin sensitisation.

Skin Sensitisation

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 Due to partial or complete lack of data the classification is not possible.

ACGIH Carcinogens

Magnesium stearate (CAS 557-04-0)	A4 Not classifiable as a human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

Reproductive toxicity 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.
Narcotic effects	Due to lack of data the classification is not possible.
Chronic effects	Prolonged inhalation may be harmful. May cause damage to organs through prolonged or repeated exposure.
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.

Section 12: Ecological information

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

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 for this product. The following information is available for the individual ingredients.

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 methods Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Dispose of contents/container in accordance with local/regional/national/international regulations. 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.

Residual waste 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.

Special precautions to be taken during disposal Dispose in accordance with all applicable regulations.

Method of disposal that should not be used None known.

Section 14: Transport information

IATA

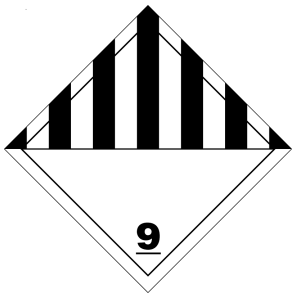
UN number	UN3077
UN proper shipping name	Environmentally Hazardous Substance, Solid, n.o.s (Maropitant citrate monohydrate)
Transport hazard class(es)	
Class	9
Subsidiary hazard	-
Packing group	III
Environmental hazards	Yes
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

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 hazard	-
Packing group	III
Environmental hazards	
Marine pollutant	Yes
EmS	F-A, S-F
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

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.

Section 15: Regulatory information

Applicable regulations Registered pursuant to the ACVM Act 1997, No. A9844.
See www.foodsafety.govt.nz for registration conditions.
Approved pursuant to the HSNO Act 1996, Code No. HSR100757.
See www.epa.govt.nz for approval controls.

New Zealand Inventory of Chemicals (NZIoC): Registration status

Magnesium stearate (CAS 557-04-0)	Does not have individual approval but may be used under an appropriate group standard

Microcrystalline cellulose (CAS 9004-34-6)	Does not have individual approval but may be used under an appropriate group standard

Section 16: Other information

Issue date	20-April-2022
Revision date	06-November-2024
Version No.	02
Key abbreviations or acronyms used	Not available.
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Revision information	This document has undergone significant changes and should be reviewed in its entirety.