

SAFETY DATA SHEET



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 (AU)	Zoetis Australia Pty Ltd ABN 94 156 476 425 Level 6, 5 Rider Boulevard Rhodes NSW 2138 AUSTRALIA
Tel	1800 814 883
Fax	(02) 8876 0444
Email	australia.animalhealth@zoetis.com
Emergency Phone	1800 814 883 (all hours)
Police and Fire Brigade	Dial 000
If ineffective	Dial Poisons Information Centre (13 1126 from anywhere in Australia)

2. Hazard(s) 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)



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/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 CENTRE or doctor/physician. 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 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.

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 Salt, Monohydrate	359875-09-5	23.2
Magnesium stearate	557-04-0	<3

4. First-aid measures

Description of necessary 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 centre 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.

Personal protection for first-aid responders 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.

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. Keep victim under observation. Symptoms may be delayed.

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.

General fire hazards No unusual fire or explosion hazards noted.

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

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained.

For emergency responders Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Keep unnecessary personnel away. Avoid dust formation. Ventilate the contaminated area. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Do not breathe dust. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see 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 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. For waste disposal, see section 13 of the SDS.

7. Handling and 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. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls and personal protection

Control parameters Follow standard monitoring procedures.

Occupational exposure limits

Zoetis

Components	Type	Value
Maropitant Citrate Salt, Monohydrate (CAS 359875-09-5)	TWA	20 µg/m ³

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/m ³	Inhalable dust.
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m ³	Inhalable fibers.

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

Components	Type	Value	Form
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m ³	Inspirable dust.
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m ³	Inspirable dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m ³
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m ³

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	STEL	20 mg/m ³	Inhalable dust.
	TWA	4 mg/m ³	Respirable dust.
		10 mg/m ³	Inhalable dust.

Biological limit values	No biological exposure limits noted for the ingredient(s).
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. 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.
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.

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	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
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.
Viscosity	Not available.
Other physical and chemical parameters	
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

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	Contact with incompatible materials. Heat, flames and sparks. High temperatures. Sunlight.
Incompatible materials	Strong oxidising agents. Fluorine.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on possible routes of exposure

Inhalation	Prolonged inhalation may be harmful.	
Skin contact	Prolonged skin contact may cause temporary irritation.	
Maropitant Citrate Salt, 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 Salt, Monohydrate	Species: Rabbit	Severity: Severe

Ingestion Expected to be a low ingestion hazard.

Symptoms related to 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.

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

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 Salt, Monohydrate (CAS 359875-09-5)		
Acute		
Dermal		
LDmin.	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 Salt, Monohydrate		Species: Rabbit Severity: Non-irritating
Serious eye damage/irritation	Causes serious eye damage.	
Eye contact		
Microcrystalline cellulose		Species: Rabbit Severity: Non-irritating
		Maropitant Citrate Salt, Monohydrate Species: Rabbit Severity: Severe
Respiratory or skin sensitisation		
Respiratory sensitisation	Not a respiratory sensitizer.	
Skin sensitisation	This product is not expected to cause skin sensitisation.	
Skin sensitisation		
Maropitant Citrate Salt, 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 Salt, 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.
Reproductive toxicity	This product is not expected to cause reproductive or developmental effects.	
Developmental effects		
Maropitant Citrate Salt, 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	Prolonged inhalation may be harmful.
Other 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.

12. Ecological information

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

Components	Species	Test results
Maropitant Citrate Salt, Monohydrate (CAS 359875-09-5)		
EC50	Daphnia magna (Water Flea)	0.6 mg/l, 1.25 Hours
IC50	Red Algae	0.23 mg/l, 7 Days
LC50	Cyprinodon variegatus (Sheepshead Minnow)	0.68 mg/l, 48 Hours
	Mysidopsis bahia (Mysid Shrimp)	0.68 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 No data available.

**Partition coefficient
n-octanol / water (log Kow)**

Maropitant Citrate Salt, Monohydrate 7.75, (Measured, Log P)

Mobility in soil No data available for this product.

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.

13. Disposal considerations

Disposal methods Avoid release to the environment. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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.

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 (see: Disposal instructions).

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

14. Transport information

ADG

Not regulated as dangerous goods.

RID

UN number 3077
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 Read safety instructions, SDS and emergency procedures before handling.

IATA

UN number 3077
UN proper shipping name Environmentally Hazardous Substance, Solid, n.o.s (Maropitant citrate monohydrate)
Transport hazard class(es)
Class 9

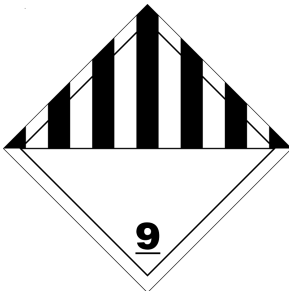
Subsidiary risk -
Packing group III
Environmental hazards Yes
Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

IMDG

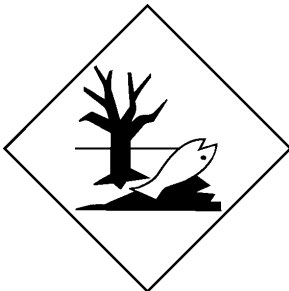
UN number 3077
UN proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Maropitant citrate monohydrate), MARINE POLLUTANT (Maropitant citrate monohydrate)
Transport hazard class(es)
Class 9
Subsidiary risk -
Packing group III
Environmental hazards
Marine pollutant Yes
EmS F-A, S-F
Special precautions for user 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; RID



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.

15. Regulatory information

Safety, health and environmental regulations

National regulations

This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals (23/12/2011).

Poison Schedule (Product) - Schedule 4

APVMA Registration Numbers: 62421, 62422, 62422, 62424

This SDS replaces version: Issued October 2016

High Volume Industrial Chemicals (HVIC)

Not listed.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations**Stockholm Convention**

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	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
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).

16. Other information**Issue date**

21-April-2017

Disclaimer

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.

Revision information

Product and Company Identification: Synonyms
 Composition / Information on Ingredients: Ingredients
 Physical & Chemical Properties: Multiple Properties
 Transport Information: Material Transportation Information
 GHS: Qualifiers