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	Veterinary product used as Anti-emetic
Recommended restrictions	Not for human use

Manufacturer/Importer/Supplier/Distributor information

Company Name (USA)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-888-963-8471
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (CA)	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	productsupport@zoetis.com
Product Support	1-800-461-0917 All Safety Data Sheets are available via our Zoetis Canada website at https://www.zoetis.ca/sds/sds.aspx
Supplier	Not available.

2. Hazard identification

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

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/vapours/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/doctor. Collect spillage.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
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.
Other hazards	None known.

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

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

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 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.
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.

5. Fire-fighting measures

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 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.

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

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.

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.

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.

8. Exposure controls/personal protection

Occupational exposure limits

Zoetis

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

US. ACGIH Threshold Limit Values

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	

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

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

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

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

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)

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

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m3	

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

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

Canada. Quebec OELs. (Ministry of Labor - Regulation respecting occupational health and safety)

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m3	Total dust.

Canada. Saskatchewan OELs (Occupational Health and Safety Regulations, 1996, Table 21)

Components	Type	Value	Form
Magnesium stearate (CAS 557-04-0)	15 minute	20 mg/m3	
	8 hour	10 mg/m3	
Microcrystalline cellulose (CAS 9004-34-6)	15 minute	20 mg/m3	Fiber.
	8 hour	10 mg/m3	Fiber.

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.

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.
Viscosity	Not available.
Other information	
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	Hazardous polymerisation does not occur.
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 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)
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 or skin sensitisation

Canada - Alberta OELs: Irritant

Magnesium stearate (CAS 557-04-0)	Irritant
Microcrystalline cellulose (CAS 9004-34-6)	Irritant

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 This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

ACGIH Carcinogens

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

Canada - Manitoba OELs: carcinogenicity

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

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 cadiovascular 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 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.

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.

14. Transport information

TDG

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.

15. Regulatory information

Canadian regulations This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Precursor Control Regulations

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 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

Country(s) or region	Inventory name	On inventory (yes/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

Revision date 20-April-2022

Version No. 02

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

Identification: Recommended restrictions
Composition / Information on Ingredients: Ingredients
Composition/information on ingredients: Component information
Accidental release measures: Methods and materials for containment and cleaning up
Handling and storage: Conditions for safe storage, including any incompatibilities
Toxicological information: Acute toxicity
Toxicological information: Reproductivity
Toxicological information: Ingestion
Ecological information: Bioaccumulative potential
Disposal considerations: Disposal instructions
GHS: Classification