SAFETY DATA SHEET

1. Identification

Product identifier **Cerenia Injection**

Other means of identification

Synonyms CERENIA * Cerenia® (maropitant citrate) Injectable Solution * Cerenia® Injectable Solution * Maropitant Citrate Solution for Injection * Cerenia® Injection

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 2A
	Sensitization, skin	Category 1
	Specific target organ toxicity following repeated exposure	Category 2 (cardiovascular system, liver)
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 3
	Hazardous to the aquatic environment, long-term hazard	Category 3

Label elements

Signal word Warning

Hazard statement Causes serious eye irritation. May cause an allergic skin reaction. May cause damage to organs (cardiovascular system, liver) through prolonged or repeated exposure. Harmful to aquatic life with long lasting effects.

Precautionary statement

Prevention	Do not breathe mist or vapour. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wear eye protection/face protection. Wear protective gloves.
Response	Get medical advice/attention if you feel unwell. IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Supplemental information	Based on findings in animal studies, this compound may cause rare but potentially serious cardiac effects in human clinical use. Sulfobutylether b-cyclodextrin sodium (SBECD) has been associated with toxic effects in the kidney.
Other hazards	None known.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Sulfobutylether b-cyclodextrin sodium (SBECD)		7585-39-9	<10
Maropitant Citrate Salt, Monohydrate		359875-09-5	1.4
m-Cresol		108-39-4	<0.5

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. If breathing is difficult, trained personnel should give oxygen.
Skin contact	Remove contaminated clothing immediately and wash skin with soap and water. Get medical attention if irritation develops and persists. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Wash contaminated clothing 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 if irritation develops and persists.
Ingestion	Rinse mouth. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconsious person.
Most important symptoms/effects, acute and delayed	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Mild skin irritation. May cause an allergic skin reaction. Dermatitis. Rash. Prolonged exposure may cause chronic effects.
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. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

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	Move containers from fire area if you can do so without risk.
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. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Avoid breathing mist or vapour. Avoid contact with eyes, skin, and clothing. Ventilate the contaminated area. 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

Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Clean surface thoroughly to remove residual contamination.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). 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

Ensure adequate ventilation. Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapour. Avoid accidental injection. Avoid prolonged exposure. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash thoroughly after handling. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Keep away from heat, sparks and open flame. Store below 30°C Protect from light and freezing. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

Zoetis

Components	Type	Value
Maropitant Citrate Salt, Monohydrate (CAS 359875-09-5)	TWA	20 µg/m³
Sulfobutylether b-cyclodextrin sodium (SBECD) (CAS 7585-39-9)	TWA	3000 µg/m3

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
m-Cresol (CAS 108-39-4)	TWA	20 mg/m3	Inhalable fraction and vapour.

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

Components	Type	Value
m-Cresol (CAS 108-39-4)	TWA	22 mg/m3 5 ppm

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

Components	Type	Value
m-Cresol (CAS 108-39-4)	TWA	10 mg/m3

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

Components	Type	Value	Form
m-Cresol (CAS 108-39-4)	TWA	20 mg/m3	Inhalable fraction and vapour.

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

Components	Type	Value	Form
m-Cresol (CAS 108-39-4)	TWA	20 mg/m3	Inhalable fraction and vapour.

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

Components	Type	Value	Form
m-Cresol (CAS 108-39-4)	TWA	20 mg/m3	Inhalable fraction and vapour.

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

Components	Type	Value
m-Cresol (CAS 108-39-4)	15 minute	10 ppm
	8 hour	5 ppm

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

Exposure guidelines

Canada - Alberta OELs: Skin designation

m-Cresol (CAS 108-39-4) Can be absorbed through the skin.

Canada - British Columbia OELs: Skin designation

m-Cresol (CAS 108-39-4) Can be absorbed through the skin.

Canada - Manitoba OELs: Skin designation

m-Cresol (CAS 108-39-4) Danger of cutaneous absorption

Canada - Ontario OELs: Skin designation

m-Cresol (CAS 108-39-4) Can be absorbed through the skin.

Canada - Quebec OELs: Skin designation

m-Cresol (CAS 108-39-4) Can be absorbed through the skin.

Canada - Saskatchewan OELs: Skin designation

m-Cresol (CAS 108-39-4) Can be absorbed through the skin.

US ACGIH Threshold Limit Values: Skin designation

m-Cresol (CAS 108-39-4) Danger of cutaneous absorption

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.

Individual protection measures, such as personal protective equipment

Eye/face protection If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection Wear suitable gloves. Wear impervious gloves if skin contact is possible.

Other Wear suitable protective clothing. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. 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. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Appearance aqueous solution

Physical state Liquid.

Form Liquid.

Colour Clear, colorless to pale yellow

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 applicable.
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	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Heat, flames and sparks. High temperatures.
Incompatible materials	Strong oxidising agents.
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 May cause damage to organs through prolonged or repeated exposure by inhalation.

Skin contact May cause an allergic skin reaction.

Maropitant Citrate Salt, Monohydrate	Species: Rabbit Severity: Non-irritating
Sulfobutylether b-cyclodextrin sodium (SBECD)	Species: Rabbit Severity: Non-irritating
m-Cresol	Species: Rabbit Severity: Severe

Eye contact Causes serious eye irritation.

Sulfobutylether b-cyclodextrin sodium (SBECD)	Species: Rabbit Severity: Non-irritating

Eye contact

Maropitant Citrate Salt, Monohydrate	Species: Rabbit Severity: Severe
m-Cresol	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. Mild skin irritation. May cause an allergic skin reaction. Dermatitis. Rash.

Information on toxicological effects

Acute toxicity Not acutely toxic

Components	Species	Test Results
Maropitant Citrate Salt, 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)]
m-Cresol (CAS 108-39-4)		
Acute		
Dermal		
LD50	Rabbit	2050 mg/kg
Inhalation		
LC50	-	58 mg/m3, 8 Hours
Oral		
LD50	Rat	242 mg/kg
Sulfobutylether b-cyclodextrin sodium (SBECD) (CAS 7585-39-9)		
Acute		
Intravenous		
LD50	Rat/Mouse	> 2000 mg/kg
Oral		
LD50	Rat	> 2000 mg/kg
Chronic		
Intravenous		
NOAEL	Dog	600 mg/kg/day, 6 months Kidney
		120 mg/kg/day, 1 months Kidney
	Rat	600 mg/kg/day, 6 months Kidney Liver
		160 mg/kg/day, 1 months Kidney

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Corrosivity

Maropitant Citrate Salt, Monohydrate	Species: Rabbit Severity: Non-irritating

Serious eye damage/eye irritation Causes serious eye irritation.

Eye contact

Sulfobutylether b-cyclodextrin sodium (SBECD)	Species: Rabbit Severity: Non-irritating
Maropitant Citrate Salt, Monohydrate	Species: Rabbit Severity: Severe
m-Cresol	Species: Rabbit Severity: Severe

Respiratory or skin sensitisation

Respiratory sensitisation Not a respiratory sensitiser.

Skin sensitisation May cause an allergic skin reaction.

Skin Sensitisation

Maropitant Citrate Salt, Monohydrate	GPMT Species: Guinea Pig Severity: Negative
Sulfobutylether b-cyclodextrin sodium (SBECD)	Species: Guinea Pig Severity: positive

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

Sulfobutylether b-cyclodextrin sodium (SBECD)	Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella , E. coli In Vitro Chromosome Aberration Result: Negative Species: Human lymphocytes In Vivo Micronucleus Result: Negative Species: Mouse Bone Marrow Mammalian Cell Mutagenicity Result: Negative Species: Chinese Hamster Ovary (CHO) cells HGPRT
Maropitant Citrate Salt, 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

m-Cresol (CAS 108-39-4)	A4 Not classifiable as a human carcinogen.

Canada - Manitoba OELs: carcinogenicity

m-Cresol (CAS 108-39-4)	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 Salt, Monohydrate	150 mg/kg/day Embryo / Fetal Development, Not teratogenic Result: NOEL Species: Rat
Sulfobutylether b-cyclodextrin sodium (SBECD)	1500 mg/kg/day Embryo / Fetal Development, Not Teratogenic Result: NOAEL Species: Rabbit Organ: Intravenous

Developmental effects

Sulfobutylether b-cyclodextrin sodium (SBECD)	1500 mg/kg/day Fertility and Embryonic Development, No effects at maximum dose Result: NOAEL Species: Rat Organ: Intravenous 600 mg/kg/day Prenatal & Postnatal Development, Maternal Toxicity Result: NOAEL Species: Rat Organ: Intravenous

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 Based on findings in animal studies, this compound may cause rare but potentially serious cardiac effects in human clinical use. Sulfobutylether b-cyclodextrin sodium (SBECD) has been associated with toxic effects in the kidney.

12. Ecological information

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

Components		Species	Test Results
Maropitant Citrate Salt, 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
m-Cresol (CAS 108-39-4)			
Aquatic			
Crustacea	EC50	Scud (Gammarus fasciatus)	7 mg/l, 48 hours
Acute			
Crustacea	EC50	Scud (Gammarus fasciatus)	7 mg/l, 48 hours
Fish	LC50	Rainbow trout,donaldson trout (Oncorhynchus mykiss)	8.9 mg/l, 96 hours
Sulfobutylether b-cyclodextrin sodium (SBECD) (CAS 7585-39-9)			
	IC50	Green algae	> 100 mg/l, Hours
Aquatic			
Crustacea	EC50	Daphnia magna (Water Flea)	> 96 mg/l, 48 Hours
Fish	LC50	Oncorhynchus mykiss (rainbow trout)	> 220 mg/l, 96 Hours

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential See below

Partition coefficient n-octanol / water (log Kow)

Maropitant Citrate Salt, Monohydrate	5.12, (+/- 0.01)

Mobility in soil No data available.

Adsorption

Soil/Sediment Sorption - Log Koc

Maropitant Citrate Salt, 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 The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

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

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

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
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 19-April-2017

Revision date 24-March-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: Disclosure Overrides
Composition/information on ingredients: Component information
First-aid measures: Ingestion
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