

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 (US)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (EU)	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Serious eye damage/eye irritation	Category 2A
	Sensitization, skin	Category 1
	Specific target organ toxicity, 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
OSHA defined hazards	Not classified.	

Label elements



Signal word	Warning
Hazard statement	May cause an allergic skin reaction. Causes serious eye irritation. 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 vapor. Wash thoroughly after handling. Contaminated work clothing must 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. Wash contaminated clothing before reuse.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	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.

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

Composition comments In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center 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. 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 (CO ₂).
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 vapor. 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. For personal protection, see section 8 of the SDS.

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. Following product recovery, flush area with water.

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 vapor. 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 in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Zoetis

Components	Type	Value
Maropitant Citrate Salt, Monohydrate (CAS 359875-09-5)	TWA	20 µg/m ³
Sulfobutylether b-cyclodextrin sodium (SBECD) (CAS 7585-39-9)	TWA	3000 µg/m ³

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value
m-Cresol (CAS 108-39-4)	PEL	22 mg/m ³ 5 ppm

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
m-Cresol (CAS 108-39-4)	TWA	20 mg/m ³	Inhalable fraction and vapor.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
m-Cresol (CAS 108-39-4)	TWA	10 mg/m ³ 2.3 ppm

Biological limit values

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

Exposure guidelines

US - California OELs: Skin designation

m-Cresol (CAS 108-39-4)

Can be absorbed through the skin.

US - Minnesota Haz Subs: Skin designation applies

m-Cresol (CAS 108-39-4)

Skin designation applies.

US - Tennessee 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)

Can be absorbed through the skin.

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

m-Cresol (CAS 108-39-4)

Can be absorbed through the skin.

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.

Color

Clear, colorless to pale yellow

Odor

Not available.

Odor 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**Flammability limit - lower (%)**

Not available.

Flammability limit - upper (%)

Not available.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapor pressure

Not available.

Vapor density

Not available.

Relative density

Not available.

Solubility(ies)**Solubility (water)**

Not available.

Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

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 oxidizing 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
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Sulfobutylether b-cyclodextrin sodium (SBECD)	Species: Rabbit Severity: Non-irritating
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m-Cresol	Species: Rabbit Severity: Severe
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Eye contact Causes serious eye irritation.

Sulfobutylether b-cyclodextrin sodium (SBECD)	Species: Rabbit Severity: Non-irritating
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Maropitant Citrate Salt, Monohydrate	Species: Rabbit Severity: Severe
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m-Cresol	Species: Rabbit Severity: Severe
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Ingestion Expected to be a low ingestion hazard.

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

Components	Species	Test Results
Maropitant Citrate Salt, Monohydrate (CAS 359875-09-5)		
Acute		
Dermal		
LDmin.	Rat	> 2000 mg/kg
Oral		
LDmin.	Rat	1000 mg/kg (Maropitant methanesulfonate salt)

Components	Species	Test Results
<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)]
m-Cresol (CAS 108-39-4)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	2050 mg/kg
Oral		
LD50	Rat	242 mg/kg
Sulfobutylether b-cyclodextrin sodium (SBECD) (CAS 7585-39-9)		
<u>Acute</u>		
Intravenous		
LD50	Rat/Mouse	> 2000 mg/kg
Oral		
LD50	Rat	> 2000 mg/kg
<u>Chronic</u>		
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 sensitization		
Respiratory sensitization	Not a respiratory sensitizer.	
Skin sensitization	May cause an allergic skin reaction.	
Skin sensitization		
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.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

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

Sulfobutylether b-cyclodextrin sodium (SBECD)

1500 mg/kg/day Embryo / Fetal Development, Not Teratogenic

Result: NOAEL

Species: Rabbit

Organ: Intravenous

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)			
	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
m-Cresol (CAS 108-39-4)			
Aquatic			
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)			
	EC50	Daphnia magna (Water Flea)	> 96 mg/L, 48 Hours
	IC50	Green algae	> 100 mg/L, Hours
	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 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.

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. 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.

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 (see: Disposal instructions).

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

14. Transport information

DOT

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

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

m-Cresol (CAS 108-39-4)

Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes

Delayed Hazard - Yes

Fire Hazard - No

Pressure Hazard - No

Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

m-Cresol (CAS 108-39-4)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

FEMA Priority Substances Respiratory Health and Safety in the Flavor Manufacturing Workplace

m-Cresol (CAS 108-39-4)

Low priority

US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

m-Cresol (CAS 108-39-4)

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, including date of preparation or last revision

Issue date 04-19-2017

Version # 01

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 This document has undergone significant changes and should be reviewed in its entirety.