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

Veterinary product used as Anti-emetic Recommended use

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

Emergency telephone

and Drug Center

1-866-531-8896 1-888-963-8471

Product Support/Technical

Services

numbers

CHEMTREC (24 hours): 1-800-424-9300

Zoetis Belgium S.A. Company Name (EU)

> Rue Laid Burniat 1 1348 Louvain-la-Neuve

Belgium

+32 10 808080 Telephone:

Emergency telephone

number

International CHEMTREC (24 hours): +1-703-527-3887

International CHEMTREC (24 hours): +1-703-527-3887

VMIPSrecords@zoetis.com Contact E-Mail

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

Hazardous to the aquatic environment,

Category 3

Category 3

long-term hazard

OSHA defined hazards Not classified.

Label elements



Signal word

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.

Material name: Cerenia Injection

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 informationBased 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. Call a physician or poison control center immediately. Only induce vomiting at the

instruction of medical personnel. Never give anything by mouth to an unconscious person.

instruction of medical personner. Never give anything by mouth to an unconscious person.

Most importantSevere 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.

delayed 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 informationFor 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 During fire, gases hazardous to health may be formed.

the chemical
Special protective equipment

and precautions for firefighters

Move containers from fire area if you can do so without risk.

Fire fighting equipment/instructions

·

Specific methods

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

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

General fire hazards No unusual fire or explosion hazards noted.

Material name: Cerenia Injection SDS US

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.

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.

Environmental precautions

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

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 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

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	Туре	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. OSHA Table Z-1 Limits for Air	Contaminants (29 CFR 1910.	1000)	
Components	Туре	Value	
m-Cresol (CAS 108-39-4)	PEL	22 mg/m3	
		5 ppm	
US. ACGIH Threshold Limit Value	S		
Components	Туре	Value	Form
m-Cresol (CAS 108-39-4)	TWA	20 mg/m3	Inhalable fraction and vapor.
US. NIOSH: Pocket Guide to Cher	nical Hazards		
Components	Туре	Value	
m-Cresol (CAS 108-39-4)	TWA	10 mg/m3	
·		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.

Material name: Cerenia Injection Version #: 02 Revision date: 03-24-2022 Issue date: 04-19-2017 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) Danger of cutaneous absorption

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

Appropriate engineering

controls

Not available.

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.

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates

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.

No personal respiratory protective equipment normally required. In case of insufficient ventilation, Respiratory protection

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

Not available. Odor **Odor threshold** Not available. Not available. nΗ Not available. Melting point/freezing point Initial boiling point and boiling Not available.

range

Flash point Not available. **Evaporation rate** Not available. Not applicable. Flammability (solid, gas) Upper/lower flammability or explosive limits

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 Not available.

(n-octanol/water)

Material name: Cerenia Injection

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 avoidContact 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

Sulfobutylether b-cyclodextrin sodium (SBECD) Species: Rabbit

Severity: Non-irritating

m-Cresol Species: Rabbit

Severity: Severe

Eve contact Causes serious eye irritation.

Sulfobutylether b-cyclodextrin sodium (SBECD)

Species: Rabbit

Severity: Non-irritating

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)

<u>Acute</u>

Dermal

LD50 Rat > 2000 mg/kg

Oral

LDmin. Rat 1000 mg/kg (Maropitant methanesulfonate

salt)

Material name: Cerenia Injection SDS US

Components Species Test Results

Subchronic

Oral

NOAEL Dog 5 mg/kg/day, 3 months [Target organ(s):

Cardiovascular system (Maropitant

methanesulfonate salt)]

Rat 5 mg/kg/day, 3 months [Target organ(s):

Liver (Maropitant methanesulfonate salt)]

m-Cresol (CAS 108-39-4)

<u>Acute</u>

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 Causes serious eye irritation.

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 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

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

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.

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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 aqua	atic life with long	lasting effects.	Avoid release to	the environment.
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Components		Species	Test Results
Maropitant Citrate Salt, Mon	ohydrate (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
n-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-cyclodextri	in sodium (SBE	CD) (CAS 7585-39-9)	
	IC50	Green algae	> 100 mg/L, Hours
Aquatic			
Crustacea	EC50	Daphnia magna (Water Flea)	> 96 mg/L, 48 Hours
Orasiacca			

Per

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.

Material name: Cerenia Injection

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

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to

Not established.

Annex II of MARPOL 73/78 and

the IBC Code

15. Regulatory information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

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 1910.1001-1053)

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

chemical

Classified hazard Serious eye damage or eye irritation Respiratory or skin sensitization categories

Yes

Specific target organ toxicity (single or repeated exposure)

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

Not regulated.

(SDWA)

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

m-Cresol (CAS 108-39-4) Low priority

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material US state regulations

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

On inventory (yes/no)* Country(s) or region Inventory name Australia Australian Inventory of Industrial Chemicals (AICIS) Nο Canada Domestic Substances List (DSL) No

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Country(s) or region Inventory name On inventory (yes/no)* Canada Non-Domestic Substances List (NDSL) China Inventory of Existing Chemical Substances in China (IECSC) No European Inventory of Existing Commercial Chemical Europe No Substances (EINECS)

European List of Notified Chemical Substances (ELINCS) Europe 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 No

(PICCS)

Taiwan Taiwan Chemical Substance Inventory (TCSI) No United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory No

16. Other information, including date of preparation or last revision

04-19-2017 Issue date 03-24-2022 **Revision date**

Version # 02

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while Disclaimer

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.

Identification: Recommended restrictions **Revision information**

> 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

Version #: 02 Revision date: 03-24-2022 Issue date: 04-19-2017

^{*}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).