SAFETY DATA SHEET

Section 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 of the chemical and restrictions on use

Recommended use Veterinary product used as Anti-emetic

Restrictions on use Not for human use

Details of manufacturer or importer

Company Name (NZ) Zoetis New Zealand Limited
Level 4, 8 Mahuhu Crescent
Auckland Central
Auckland 1010, New Zealand

Telephone No. 0800 963 847 (Business Hours)

Emergency No. (National Poisons Centre) 0800 POISON (0800 764 766)

Emergency No. (Emergency Services) In an emergency dial 111

Section 2: Hazard identification

Classification of the hazardous chemical

Physical hazards	Not classified.	
Health hazards	Serious eye damage/eye irritation	Category 2
	Sensitization, skin	Category 1
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 3
	Hazardous to the aquatic environment, long-term hazard	Category 3

Label elements, including precautionary statements

Hazard symbol(s)

Exclamation mark

Signal word Warning

Hazard statement(s) Causes serious eye irritation. May cause an allergic skin reaction. Harmful to aquatic life with long lasting effects.

Precautionary statement(s)

Prevention Avoid breathing 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 IF ON SKIN: Wash with plenty of soap and 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.

Other hazards which do not result in classification None.

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.

Section 3: Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
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

Section 4: First-aid measures

Description of necessary 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.

Personal protection for first-aid responders 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. You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call.

Symptoms caused by exposure 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.

Medical attention and special treatment Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

Section 5: Fire-fighting measures

Extinguishing media

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for fire fighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Move containers from fire area if you can do so without risk.

Hazchem code None.

Hazards from combustion products None.

General fire hazards No unusual fire or explosion hazards noted.

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

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away.

For emergency responders Ensure adequate ventilation. Avoid contact with eyes, skin, and clothing. Do not breathe mist or vapour. Ventilate the contaminated area. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protection recommended in Section 8 of the SDS.

Environmental precautions Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up

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.

Section 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).

Section 8: Exposure controls/personal protection

Control parameters

Follow standard monitoring procedures.

Occupational exposure limits

Zoetis

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

New Zealand. OELs (Workplace Exposure Standards and Biological Exposure Indices)

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

US. ACGIH Threshold Limit Values (TLV)

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

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

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

Biological limit values

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

Exposure guidelines

New Zealand WES: Skin designation

m-Cresol (CAS 108-39-4) — Skin absorption can be significant.

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, for example personal protective equipment (PPE)

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.
Hygiene measures	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Contaminated work clothing should not be allowed out of the workplace.

Section 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.
Kinematic viscosity	Not available.
Other physical and chemical parameters	
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

Section 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.

Section 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

Skin contact

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
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	Rat	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 Causes mild skin 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 irritation Not available.

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 Due to partial or complete lack of data the classification is not possible.

ACGIH Carcinogens

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

IARC Monographs. Overall Evaluation of Carcinogenicity

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

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 Not classified.

Aspiration hazard Not an aspiration hazard.

Narcotic effects None known.

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.

Section 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 for this product.

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.

Section 13: Disposal considerations

Disposal methods 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.

Residual waste Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner.

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

Special precautions to be taken during disposal Dispose in accordance with all applicable regulations.

Method of disposal that should not be used None known.

Section 14: Transport information

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.

Section 15: Regulatory information

Applicable regulations Registered pursuant to the ACVM Act 1997, No. A009845
See www.foodsafety.govt.nz for registration conditions.
Approved pursuant to the HSNO Act, No. HSR100757.
See www.epa.govt.nz for approval controls.

New Zealand Inventory of Chemicals (NZIoC): Registration status

m-Cresol (CAS 108-39-4)	HSNO Approved
Sulfobutylether b-cyclodextrin sodium (SBECD) (CAS 7585-39-9)	May be used as a single component chemical under an appropriate group standard

Section 16: Other information

Issue date 24-March-2022

Revision date 08-September-2023

Version No. 02

Key abbreviations or acronyms used Not available.

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 Section 4: First-aid measures: Personal protection for first-aid responders
Section 15: Regulatory information: Applicable regulations