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 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 (AU) Zoetis Australia Pty Ltd
ABN 94 156 476 425
Level 6, 5 Rider Boulevard
Rhodes NSW 2138 AUSTRALIA

Tel 1800 814 883

Fax (02) 8876 0444

Email australia.animalhealth@zoetis.com

Emergency Phone 1800 814 883 (all hours)

Police and Fire Brigade Dial 000

If ineffective Dial Poisons Information Centre (13 1126 from anywhere in Australia)

2. Hazard(s) identification

Classification of the hazardous chemical

Physical hazards	Not classified.	
Health hazards	Serious eye damage/eye irritation	Category 2A
	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) May cause an allergic skin reaction. Causes serious eye irritation. 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 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

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

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. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.
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.
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.

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.
General fire hazards	No unusual fire or explosion hazards noted.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS. 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.

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. 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.

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

8. Exposure controls and 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

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

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

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

US. ACGIH Threshold Limit Values

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

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

Exposure guidelines

Australia 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.

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.

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	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
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 physical and chemical parameters

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 possible routes of exposure

Inhalation	Prolonged inhalation may be harmful.	
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
Maropitant Citrate Salt, Monohydrate		Species: Rabbit Severity: Severe
m-Cresol		Species: Rabbit Severity: Severe
Ingestion	Expected to be a low ingestion hazard.	

Symptoms related to 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.
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)
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)]

Components	Species	Test results
m-Cresol (CAS 108-39-4)		
Acute		
Dermal		
LD50	Rabbit	2050 mg/kg
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/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 sensitizer.

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

Mutagenicity

Sulfobutylether b-cyclodextrin sodium (SBECD)	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.

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 Not classified.

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful.

Other 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

Components		Species	Test results
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 for this product.

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 methods 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.

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 (see: Disposal instructions).

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

14. Transport information

ADG

Not regulated as dangerous goods.

RID

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

Safety, health and environmental regulations

National regulations This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals (23/12/2011).

Poison Schedule (Product) - Schedule 4

APVMA Registration Number: 61840

This SDS replaces version: Issued October 2016

Australia Medicines & Poisons Appendix E

CRESOLS (CAS 108-39-4)

Australia Medicines & Poisons Schedule 2

PHENOL, OR ANY HOMOLOGUE BOILING BELOW 220°C (CAS 108-39-4)

Australia Medicines & Poisons Schedule 5

PHENOL, INCLUDING CRESOLS AND XYLENOLS AND ANY OTHER HOMOLOGUE OF PHENOL BOILING BELOW 220°C (CAS 108-39-4)

Australia Medicines & Poisons Schedule 6

PHENOL, INCLUDING CRESOLS AND XYLENOLS AND ANY OTHER HOMOLOGUE OF PHENOL BOILING BELOW 220.DEGREE.C, EXCEPT WHEN SEPARATELY SPECIFIED IN THESE SCHEDULES (CAS 108-39-4)

High Volume Industrial Chemicals (HVIC)

Not listed.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Resricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

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 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

Issue date 19-April-2017

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	Product and Company Identification: Synonyms Composition / Information on Ingredients: Ingredients GHS: Classification