

SAFETY DATA SHEET

Zoetis New Zealand Limited



Section 1: Identification of the Substance and Supplier

Trade Name:	CERENIA® Injectable Solution
ACVM Registration No.:	A009845
Classification:	Restricted Veterinary Medicine (RVM)
Recommended Use:	Injectable anti-emetic for prevention of nausea and vomiting in dogs and cats.
Company Details:	Zoetis New Zealand Limited
Address:	Level 4, 8 Mahuhu Crescent Auckland Central Auckland 1010 New Zealand
Telephone No.:	0800 963 847 (Business Hours)
Emergency Telephone No.:	National Poisons Centre: 0800 POISON (0800 764 766) Emergency Services: In an emergency dial 111
Date of Preparation:	01 July 2019

Section 2: Hazards Identification

Hazard Classification:	6.5B, 6.9B, 9.1C
Priority Identifier(s):	WARNING – KEEP OUT OF REACH OF CHILDREN ECOTOXIC
Secondary Identifier(s):	6.5B May cause an allergic skin reaction. Avoid skin contact. 6.9B May cause target organ damage from repeated oral exposure at high doses. 9.1C Harmful to aquatic life with long-lasting effects. Avoid contamination of any water supply with product or empty container.

Section 3: Composition / Information on Ingredients

Chemical Identity of Ingredients

Ingredient	CAS No.	Concentration
Maropitant citrate	359875-09-5	14.484 mg/mL
Sulfobutylether β -cyclodextrin sodium (SBECD)	7585-39-9	Proprietary
Metacresol	108-39-4	Proprietary
Other ingredients determined not to be hazardous.	-	-

This is a commercial product whose exact ratio of components may vary.
Trace quantities of impurities are also likely.

Section 4: First Aid Measures

Necessary First Aid Measures:	<p>For advice contact the National Poisons Centre at 0800 POISON (0800 764 766) or a doctor immediately. If the patient is not breathing begin artificial respiration and seek medical advice immediately. Never give fluids or induce vomiting if a patient is unconscious or convulsing, regardless of injury.</p> <p>Self-Injection: Immediate medical advice should be sought on the management of all instances of accidental self-injection, particularly those near a joint or associated with bruising. Allow the wound to bleed freely and avoid squeezing the injection site to avoid spread of the product. Clean the wound thoroughly with soap and water, then keep it clean and dry.</p> <p>Ingestion: DO NOT induce vomiting. If the patient is conscious wash mouth out with water. Do not give anything by mouth to an unconscious person. Seek medical advice immediately.</p> <p>Eye Contact: Flush the eye(s) out with running water for at least 15 minutes. Removal of contact lenses should be done with caution within 5 minutes of exposure. If symptoms develop seek medical advice immediately.</p> <p>Skin Contact: Remove any contaminated clothing and wash the affected area immediately with soap and water. If symptoms develop seek medical advice immediately.</p> <p>Inhalation: Move the patient to fresh air. If symptoms develop seek medical advice immediately.</p>
Poisoning Symptoms:	No information regarding the symptoms of poisoning is available for this product.
Workplace Facilities:	No specific facilities required. Standard emergency equipment must be available.
Hygiene Practices:	Avoid self-injection, ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while using this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.
Notes for Medical Personnel:	Accidental self-injection may lead to an inflammatory response and deep injections, particularly those near a joint or associated with bruising, should be treated medically or surgically.

Section 5: Fire-Fighting Measures

Type of hazard:	This product is not flammable; however, fine particles (such as dusts and mists) may fuel fires/explosions.
Fire Hazard Properties:	Toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides may be generated by thermal decomposition or combustion.
Regulatory Requirements:	Not applicable.
Extinguishing Media & Methods:	Use dry chemical, foam, carbon dioxide or water to extinguish fires involving this product.
Hazchem Code:	Not allocated.
Recommended Protective Clothing:	During large-scale fire fighting operations wear approved positive pressure, self-contained breathing apparatus and full protective turn-out gear.

Section 6: Accidental Release Measures

Personal Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment to minimise exposure. This may include eye protection, chemically resistant gloves, boots and overalls.
Environmental Precautions:	Prevent material from entering surface water drains or waterways. If a significant quantity of material enters drains, advise emergency services.
Procedure for Spills:	<ol style="list-style-type: none">1. Non-essential personnel should be evacuated from the affected area.2. Stop leak and contain the source of spill if it is safe to do so. Reposition any leaking containers to minimise further leakage.3. Absorb the spill with an absorbent material (e.g. sand).4. Collect the spilled material into labelled containers for disposal, minimising dust generation.5. Decontaminate the spill area thoroughly with detergent and water, preventing runoff from entering drains.
Procedure for Disposal:	Contaminated material must be disposed of at an approved landfill or other approved facility in accordance with local, regional and national requirements. Avoid contamination of any water supply with product or empty container.

Section 7: Handling and Storage

Handling

Precautions for Safe Handling:	No special technical protective measures required. No special handling advice required.
Regulatory Requirements:	Not required.
Handling Practices:	Avoid self-injection, ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while handling this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.
Approved Handlers:	Approved handlers are not required for this product.

Storage

Conditions for Safe Storage:	Store below 30°C (Room Temperature). Keep out of reach of children. Store in a well ventilated area in the original container, tightly closed, away from foodstuffs.
Store Site Requirements:	No additional requirements.
Packaging:	Store in the original container, away from foodstuffs.

Section 8: Exposure Control / Personal Protection

Always Read and Follow the Label Instructions and Warnings

Workplace Exposure Guidelines	
Workplace Exposure Standards:	<p>Maropitant citrate monohydrate:</p> <ul style="list-style-type: none">• Pfizer OEL TWA-8 hr: 0.2 mg/m³ (as free base) <p>Sulfobutylether β-cyclodextrin sodium:</p> <ul style="list-style-type: none">• Pfizer OEL TWA-8 hr: 3.0 mg/m³ <p>Metacresol:</p> <ul style="list-style-type: none">• ACGIH Threshold Limit Value (TWA): 5 ppm TWA• ACGIH – Skin Absorption Designation: Listed
Application in the Workplace:	The nature of this product makes it unlikely that this level will be approached during normal handling.
Exposure Standards Outside the Workplace:	None set.
Engineering Controls:	Engineering controls should be used as the primary means to control exposures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.
Personal Protection:	<p>The following instructions are for those coming into frequent and / or lengthy contact with this product. For occasional handling employ precautions suitable for the conditions under which the product is being handled.</p> <p>Hands: Impervious gloves are recommended if skin contact is possible and for bulk processing operations.</p> <p>Eyes: It is always prudent to utilise protective eyewear.</p> <p>Skin: When prolonged or frequently repeated contact could occur, utilise chemically protective clothing. Selection of specific items such as a face shield, gloves, boots, or overalls will depend on the situation.</p> <p>Respiratory: Respiratory protection is not normally required; however, if necessary utilise an air-purifying respirator that complies with NZ standards.</p>
General Hygiene:	Change work clothes regularly. Avoid self-injection, ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while handling this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.

Section 9: Physical and Chemical Properties

Appearance:	A clear, colourless to light yellow solution
Odour:	No information available
Specific Gravity / Density:	1.028 g/mL
Melting Point:	Not applicable
Boiling Point:	90°C – 100°C
pH:	4.1 – 4.7
Solubility in Water:	No information available
Flashpoint:	Not applicable. This product is not flammable.
Oxidising Properties:	Not applicable. This product is not an oxidiser.
Corrosive Properties:	Not applicable. This product is not corrosive.
Vapour Pressure:	No information available

Section 10: Stability and Reactivity

Stability of the Substance:	This product is stable under normal conditions of use.
Conditions to Avoid:	Store as recommended. No special conditions to avoid.
Material to Avoid:	No particular materials to avoid.
Hazardous Decomposition Products:	This product is unlikely to spontaneously decompose. No significant quantities of decomposition products are expected at temperatures normally achieved in a fire.
Hazardous Polymerisation:	This product is unlikely to spontaneously polymerise.
Specific Data:	No specific data available.

Section 11: Toxicological Information

HSNO Classifications

- 6.5B** May cause an allergic skin reaction. Avoid skin contact.
- 6.9B** May cause target organ damage from repeated oral exposure to high doses.

Acute Effects

Acute Toxicity:	Maropitant citrate monohydrate (Species, Route, End Point, Dose): <ul style="list-style-type: none">• Rabbit Dermal LDmin. > 2000 mg/kg• Rat Oral LDmin. 1000 mg/kg• Rat Oral LD50 > 2000 mg/kg Metacresol (Species, Route, End Point, Dose): <ul style="list-style-type: none">• Rat Oral LD50 242 mg/kg• Rabbit Dermal LD50 2050 mg/kg Sulfobutylether β-cyclodextrin sodium (Species, Route, End Point, Dose): <ul style="list-style-type: none">• Rat Oral LD50 > 2000 mg/kg• Rat/Mouse IV LD50 > 2000 mg/kg A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.
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- Irritation / Sensitisation:**
- Maropitant citrate monohydrate (Study Type, Species, Severity):
- Eye irritation Rabbit Severe
 - Skin irritation Rabbit Not irritating
 - Skin sensitisation Mouse Positive
- Metacresol (Study Type, Species, Severity):
- Eye irritation Rabbit Severe
 - Skin irritation Rabbit Severe
- Sulfobutylether β -cyclodextrin sodium (Study Type, Species, Severity):
- Eye irritation Rabbit Not irritating
 - Skin irritation Rabbit Not irritating
 - Skin sensitisation – GPMT Guinea pig Positive

Chronic / Long Term Effects

- Repeated Dose Toxicity:**
- Maropitant citrate monohydrate:
(Duration, Species, Route, Dose, End Point, Target Organ)
- 3 Month(s) Rat Oral 5 mg/kg/day NOAEL None identified
 - 3 Month(s) Dog Oral 5 mg/kg/day NOAEL Cardiovascular system
- Sulfobutylether β -cyclodextrin sodium (SBECD):
(Duration, Species, Route, Dose, End Point, Target Organ)
- 6 Month(s) Rat Intravenous 600 mg/kg/day NOAEL Kidney, Liver
 - 1 Month(s) Rat Intravenous 160 mg/kg/day NOAEL Kidney
 - 6 Month(s) Dog Intravenous 600 mg/kg/day NOAEL Kidney
 - 1 Month(s) Dog Intravenous 120 mg/kg/day NOAEL Kidney
- Reproduction & Developmental Toxicity:**
- Maropitant citrate monohydrate:
(Study Type, Species, Route, Dose, End Point, Effect(s))
- Embryo / Foetal Development Rat 75 mg/kg/day NOEL Not teratogenic
- Sulfobutylether β -cyclodextrin sodium (SBECD):
(Study Type, Species, Route, Dose, End Point, Effect(s))
- Fertility and Embryonic Development Rat Intravenous 1500 mg/kg/day NOAEL No effects at maximum dose
 - Embryo / Foetal Development Rabbit Intravenous 1500 mg/kg/day NOAEL Not Teratogenic
 - Prenatal & Postnatal Development Rat Intravenous 600 mg/kg/day NOAEL Maternal Toxicity
- Genetic Toxicity:**
- Maropitant citrate monohydrate:
(Study Type, Cell Type/Organism, Result)
- Bacterial Mutagenicity (Ames) *Salmonella* Negative
 - *In Vitro* Chromosome Aberration Human Lymphocytes Negative
 - *In Vitro* Chinese Hamster Ovary (CHO) cells Negative
- Sulfobutylether β -cyclodextrin sodium (SBECD):
(Study Type, Cell Type/Organism, Result)
- Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
 - *In Vitro* Chromosome Aberration Human Lymphocytes Negative
 - Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells HGPRT Negative
 - *In Vivo* Micronucleus Mouse Bone Marrow Negative
- Carcinogenicity:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Section 12: Ecotoxicity Information

HSNO Classifications

9.1C Harmful to aquatic life with long-lasting effects. Avoid contamination of any water supply with product or empty container.

The environmental characteristics of this material have not been fully evaluated.
Avoid contamination of any water supply with product or empty container.

Ecotoxicity Effects

Bioaccumulation & Toxicity:

Acute toxicity to aquatic organisms could occur. This material has low potential to bioaccumulate and long-term adverse effects to aquatic organisms are not expected. See aquatic toxicity data, below.

Aquatic Toxicity:

Maropitant citrate monohydrate:

(Species, Method, End Point, Duration, Result)

- Mysid Shrimp NPDES LC50 48 Hours 0.68 mg/L
- Sheepshead Minnow NPDES LC50 96 Hours 0.68 mg/L
- Red Algae NPDES IC50 7 Days 0.23 mg/L

Sulfobutylether β -cyclodextrin sodium (SBECD):

(Species, Method, End Point, Duration, Result)

- Rainbow Trout OECD LC50 96 Hours > 220 mg/L
- Daphnia magna OECD EC-50 48 Hours > 96 mg/L
- Green algae OECD IC50 72 Hours > 100 mg/L

The above aquatic toxicity studies were conducted with CJ-11,972 (free base). The effects of the two materials are predicted to be similar. A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

Toxicity to Birds:

Not applicable.

Toxicity to Soil Dwelling Organisms:

Not applicable.

Acute Toxicity to Bees:

Not applicable.

Environmental Fate

No information available.

Section 13: Disposal Considerations

Product Disposal:

Preferably dispose of product by use in accordance with label directions. Otherwise dispose of product at an approved landfill, or other approved facility in accordance with local, regional and national regulations. Avoid contamination of any water supply with product.

Container Disposal:

Dispose of empty containers by wrapping in paper and putting in garbage for disposal at an approved landfill, or other approved facility in accordance with local, regional and national regulations. Avoid contamination of any water supply with empty container. Used needles and syringes should immediately be placed in a designated and appropriately labelled "sharps" container.

Section 14: Transport Information

Dangerous Goods Classification

UN No.:	Not applicable. This product is not a dangerous good.
Class:	Not applicable. This product is not a dangerous good.
Packing Group:	Not applicable. This product is not a dangerous good.
Proper Shipping Name:	Not applicable. This product is not a dangerous good.

Section 15: Regulatory Information

HSNO Approval No.:	HSR007760
HSNO Controls:	See www.epa.govt.nz for controls
ACVM Registration No.:	A009845
ACVM Controls:	See www.foodsafety.govt.nz for registration conditions

Section 16: Other Information

Note: This product is a veterinary medicine and must therefore be used in accordance with the container label directions. A comprehensive package of toxicological and environmental data for the active ingredients of this product has been submitted to the Government health and environment authorities and has been evaluated by expert toxicologists and environmental scientists.

CONTACT POINT:	Zoetis New Zealand Limited:	0800 963 847 (Business Hours)
	National Poisons Centre:	0800 POISON (0800 764 766)
	Emergency Services:	Dial 111

This Safety Data Sheet summarises our best knowledge of the health and safety hazard information of the product and how to safely handle and use the product in the workplace. Each user should read this SDS and consider the information in the context of how the product will be handled and used in the workplace including in conjunction with other products.

PLEASE READ ALL LABELS CAREFULLY BEFORE USING PRODUCT.

If clarification of further information is needed to ensure that an appropriate risk assessment can be made, the user should contact this company.

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