

# SAFETY DATA SHEET



Revision date: 11-Feb-2014

Version: 4.0

Page 1 of 10

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Maropitant Citrate Solution for Injection

**Trade Name:** CERENIA  
**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Veterinary product used as Anti-emetic.

### Details of the Supplier of the Safety Data Sheet

Zoetis Inc.  
100 Campus Drive, P.O. Box 651  
Florham Park, New Jersey 07932 (USA)  
Rocky Mountain Poison Control Center Phone: 1-866-531-8896  
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.  
Mercuriusstraat 20  
1930 Zaventem  
Belgium

**Emergency telephone number:**  
**CHEMTREC (24 hours): 1-800-424-9300**  
**Contact E-Mail:** VMIPSrecords@zoetis.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours): +1-703-527-3887**

## 2. HAZARDS IDENTIFICATION

**Appearance:** Clear, colorless to pale yellow solution

### Classification of the Substance or Mixture

#### GHS - Classification

Serious Eye Damage/Eye Irritation: Category 2A  
Skin Sensitization: Category 1  
Specific target organ systemic toxicity (repeated exposure): Category 2  
Acute aquatic toxicity: Category 3  
Chronic aquatic toxicity: Category 3

#### EU Classification:

EU Indication of danger: Irritant

EU Symbol: Xi

EU Risk Phrases:

R43 - May cause sensitization by skin contact.  
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

### Label Elements

**Signal Word:** Warning

## SAFETY DATA SHEET

Material Name: Maropitant Citrate Solution for Injection  
Revision date: 11-Feb-2014

Page 2 of 10  
Version: 4.0

### 2. HAZARDS IDENTIFICATION

**Hazard Statements:**  
 H319 - Causes serious eye irritation  
 H317 - May cause an allergic skin reaction  
 H373 - May cause damage to organs through prolonged or repeated exposure (cardiovascular, kidneys, liver)  
 H412 - Harmful to aquatic life with long lasting effects

**Precautionary Statements:**  
 P264 - Wash hands thoroughly after handling  
 P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
 P272 - Contaminated work clothing should not be allowed out of the workplace  
 P280 - Wear protective gloves/protective clothing/eye protection/face protection  
 P260 - Do not breathe dust/fume/gas/mist/vapors/spray  
 P273 - Avoid release to the environment  
 P302+ P352 - IF ON SKIN: Wash with plenty of soap and water  
 P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention  
 P362 - Take off contaminated clothing and wash before reuse  
 P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
 P314 - Get medical attention/advice if you feel unwell  
 P501 - Dispose of contents/container in accordance with all local and national regulations



**Other Hazards**

**Short Term:** May cause eye irritation. Not expected to cause skin irritation (based on components). May cause respiratory tract irritation.

**Long Term:** Based on findings in animal studies, this compound may cause rare but potentially serious cardiac effects in human clinical use.

**Known Clinical Effects:** Sulfobutylether b-cyclodextrin sodium (SBECD) has been associated with toxic effects in the kidney.

**Australian Hazard Classification (NOHSC):** Hazardous Substance. Non-Dangerous Goods.

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%

## SAFETY DATA SHEET

Material Name: Maropitant Citrate Solution for Injection  
Revision date: 11-Feb-2014

Page 3 of 10  
Version: 4.0

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Maropitant citrate monohydrate	359875-09-5	Not Listed	N;R50/53 Xn;R48/22 Xi;R41	Eye Dam. 1, H318; STOT Rep. 2, H373; Aquatic Acute 1, H400; Aquatic Chronic 1, H410	1.40
Sulfobutylether b-cyclodextrin sodium (SBECD)	7585-39-9	231-493-2	Xi;43	Not Listed	<10
m-Cresol	108-39-4	203-577-9	T; R24/25 C; R34	Acute Tox. 3 (H301) Skin Corr. 1B (H314)	<0.5%

**Additional Information:** Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

**For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16**

### 4. FIRST AID MEASURES

**Description of First Aid Measures**

- Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Most Important Symptoms and Effects, Both Acute and Delayed**

- Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
- Medical Conditions Aggravated by Exposure:** None known

**Indication of the Immediate Medical Attention and Special Treatment Needed**

- Notes to Physician:** None

### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

**Special Hazards Arising from the Substance or Mixture**

- Hazardous Combustion Products:** Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.
- Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

**Advice for Fire-Fighters**

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Dike and collect water used to fight fire.

## SAFETY DATA SHEET

Material Name: Maropitant Citrate Solution for Injection  
Revision date: 11-Feb-2014

Page 4 of 10  
Version: 4.0

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Keep away from heat, sparks, and flame. Avoid accidental injection.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Keep container tightly closed when not in use.

**Storage Temperature:** Store as directed by product packaging.

**Specific end use(s):** No data available

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### Maropitant citrate monohydrate

Zoetis OEL TWA 8-hr 20 µg/m<sup>3</sup>

#### m-Cresol

ACGIH Threshold Limit Value (TWA) 20 mg/m<sup>3</sup>

ACGIH - Skin Absorption Designation Skin - potential significant contribution to overall exposure by the cutaneous route

Austria OEL - MAKs 5 ppm  
22 mg/m<sup>3</sup>

Denmark OEL - TWA 5 ppm  
22 mg/m<sup>3</sup>

Finland OEL - TWA 5 ppm  
22 mg/m<sup>3</sup>

Poland OEL - TWA 22 mg/m<sup>3</sup>

Portugal OEL - TWA 5 ppm

Slovakia OEL - TWA 5 ppm

Sweden OEL - TWAs 22 mg/m<sup>3</sup>

1 ppm  
4.5 mg/m<sup>3</sup>

#### Exposure Controls

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.

## SAFETY DATA SHEET

Material Name: Maropitant Citrate Solution for Injection  
Revision date: 11-Feb-2014

Page 5 of 10  
Version: 4.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Aqueous solution	<b>Color:</b>	Clear, colorless to pale yellow
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
No data available			
<b>Maropitant citrate monohydrate</b>			
Measured Log P 7.75			
<b>Decomposition Temperature (°C):</b>	No data available.		
<b>Evaporation Rate (Gram/s):</b>	No data available		
<b>Vapor Pressure (kPa):</b>	No data available		
<b>Vapor Density (g/ml):</b>	No data available		
<b>Relative Density:</b>	No data available		
<b>Viscosity:</b>	No data available		
<b>Flammability:</b>			
<b>Autoignition Temperature (Solid) (°C):</b>		No data available	
<b>Flammability (Solids):</b>		No data available	
<b>Flash Point (Liquid) (°C):</b>		No data available	
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>		No data available	
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>		No data available	
<b>Polymerization:</b>		Will not occur	

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable at ambient temperatures
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers
<b>Hazardous Decomposition Products:</b>	None known

## SAFETY DATA SHEET

Material Name: Maropitant Citrate Solution for Injection  
Revision date: 11-Feb-2014

Page 6 of 10  
Version: 4.0

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

**General Information:** Toxicological properties of the formulation have not been investigated. The information included in this section describes the potential hazards of various forms of the active ingredient. The remaining information describes the potential hazards of the individual ingredients.

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### m-Cresol

Rat Oral LD50 242 mg/kg  
Rabbit Dermal LD50 2050mg/kg

##### Maropitant citrate monohydrate

Rat Dermal LDmin. > 2000 mg/kg

##### Sulfobutylether b-cyclodextrin sodium (SBECD)

Rat Oral LD50 > 2000 mg/kg  
Rat/Mouse IV LD50 > 2000mg/kg

##### Maropitant methanesulfonate salt

Rat Oral LDmin. 1000 mg/kg

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### m-Cresol

Skin Irritation Rabbit Severe  
Eye Irritation Rabbit Severe

##### Maropitant citrate monohydrate

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Non-irritating  
Skin Sensitization - GPMT Guinea Pig Negative

##### Sulfobutylether b-cyclodextrin sodium (SBECD)

Eye Irritation Rabbit Non-irritating  
Skin Irritation Rabbit Non-irritating  
Skin Sensitization - GPMT Guinea Pig Positive

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Sulfobutylether b-cyclodextrin sodium (SBECD)

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

##### Maropitant methanesulfonate salt

3 Month(s)	Rat	Oral	5 mg/kg/day	NOAEL	Liver
3 Month(s)	Dog	Oral	5 mg/kg/day	NOAEL	Cardiovascular system

## SAFETY DATA SHEET

Material Name: Maropitant Citrate Solution for Injection  
Revision date: 11-Feb-2014

Page 7 of 10  
Version: 4.0

### 11. TOXICOLOGICAL INFORMATION

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### **Maropitant citrate monohydrate**

Embryo / Fetal Development Rat 150 mg/kg/day NOEL Not teratogenic

##### **Sulfobutylether b-cyclodextrin sodium (SBECD)**

Fertility and Embryonic Development Rat Intravenous 1500 mg/kg/day NOEL No effects at maximum dose

Embryo / Fetal Development Rabbit Intravenous 1500 mg/kg/day NOEL Not Teratogenic

Prenatal & Postnatal Development Rat Intravenous 600 mg/kg/day NOEL Maternal Toxicity

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### **Sulfobutylether b-cyclodextrin sodium (SBECD)**

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

##### **Maropitant methanesulfonate salt**

Bacterial Mutagenicity (Ames) *Salmonella* Negative

*In Vitro* Human Lymphocytes Negative

*In Vivo* Micronucleus Mouse Bone Marrow Negative

*In Vitro* Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Negative

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## SAFETY DATA SHEET

Material Name: Maropitant Citrate Solution for Injection  
Revision date: 11-Feb-2014

Page 8 of 10  
Version: 4.0

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Harmful to aquatic life with long lasting effects. Releases to the environment should be avoided.

**Toxicity:**

**Aquatic Toxicity: (Species, Method, End Point, Duration, Result)**

**Maropitant citrate monohydrate**

<i>Mysidopsis bahia</i> (Mysid Shrimp)	NPDES	LC50	48	Hours	0.68	mg/L
<i>Cyprinodon variegatus</i> (Sheepshead Minnow)	NPDES	LC50	48	Hours	0.68	mg/L
Red Algae	NPDES	IC50	7	Days	0.23	mg/L
<i>Daphnia magna</i> (Water Flea)	EC50	1.25	Hours	0.60	mg/L	

**Sulfobutylether b-cyclodextrin sodium (SBECD)**

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	OECD	LC50	96	Hours	> 220	mg/L
<i>Daphnia magna</i> (Water Flea)	OECD	EC-50	48	Hours	> 96	mg/L
Green algae	OECD	IC50	72	Hours	> 100	mg/L

**Aquatic Toxicity Comments:** A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Maropitant citrate monohydrate**

Measured Log P 7.75

**Mobility in Soil:** No data available

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** This product contains trace quantities of m-cresol and may qualify as a RCRA Hazardous Waste. Status should be confirmed using the EPA Toxicity Characteristic Leaching Procedure (TCLP). Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. 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.

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.



## SAFETY DATA SHEET

Material Name: Maropitant Citrate Solution for Injection  
Revision date: 11-Feb-2014

Page 9 of 10  
Version: 4.0

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision B



#### Maropitant citrate monohydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Sulfobutylether b-cyclodextrin sodium (SBECD)

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-493-2

#### m-Cresol

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	100 lb
California Proposition 65	45.4 kg
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 5
	Schedule 6
	203-577-9

### 16. OTHER INFORMATION

#### Text of R phrases and GHS Classification abbreviations mentioned in Section 3

H301 - Toxic if swallowed  
H314 - Causes severe skin burns and eye damage  
H318 - Causes serious eye damage  
H373 - May cause damage to organs through prolonged or repeated exposure  
H400 - Very toxic to aquatic life  
H410 - Very toxic to aquatic life with long lasting effects

## SAFETY DATA SHEET

**Material Name: Maropitant Citrate Solution for Injection**  
**Revision date: 11-Feb-2014**

**Page 10 of 10**  
**Version: 4.0**

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T - Toxic  
C - Corrosive  
Xn - Harmful  
Xi - Irritant  
N - Dangerous for the environment

R34 - Causes burns.  
R41 - Risk of serious damage to eyes.  
R43 - May cause sensitization by skin contact.  
R24/25 - Toxic in contact with skin and if swallowed.  
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.  
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Data Sources:** The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

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.

**End of Safety Data Sheet**