

SAFETY DATA SHEET



Revision date: 12-Feb-2015

Version: 5.2

Page 1 of 10

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

Product Identifier

Material Name: Maropitant Citrate Tablets

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.

Restrictions on Use: Not for human use

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: Oval , convex peach tablets

Classification of the Substance or Mixture

GHS - Classification

Serious Eye Damage/Eye Irritation: Category 1

Specific target organ systemic toxicity (repeated exposure): Category 2

Acute aquatic toxicity: Category 2

Chronic aquatic toxicity: Category 2

EU Classification:

EU Indication of danger: Harmful
Irritant
Dangerous for the Environment

EU Symbol: Xn ; N

EU Risk Phrases:

R41 - Risk of serious damage to eyes.

R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

R51/53 - Toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

Label Elements

Signal Word: Danger

SAFETY DATA SHEET

Material Name: Maropitant Citrate Tablets
Revision date: 12-Feb-2015

Page 2 of 10
Version: 5.2

2. HAZARDS IDENTIFICATION

Hazard Statements:

H318 - Causes serious eye damage
H373 - May cause damage to organs through prolonged or repeated exposure
(cardiovascular , kidneys , liver)
H411 - Toxic to aquatic life with long lasting effects

Precautionary Statements:

P280 - Wear protective gloves/protective clothing/eye protection/face protection
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash hands thoroughly after handling
P273 - Avoid release to the environment
P314 - Get medical attention/advice if you feel unwell
P337 + P313 - If eye irritation persists: Get medical advice/attention
P310 - Immediately call a POISON CENTRE or doctor/physician
P391 - Collect spillage
P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards

Short Term:

May cause eye irritation . May cause serious damage to eyes. Irritation may occur following direct contact. Symptoms might include redness, swelling, discharge, blurred vision, pain or permanent eye damage. Dust may cause irritation to respiratory system if tablets are crushed or broken .

Long Term:

Based on findings in animal studies, this compound may cause rare but potentially serious cardiac effects in human clinical use. These effects have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

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	%
Maropitant citrate monohydrate	359875-09-5	Not Listed	N;R50/53 Xn;R48/22 Xi;R41	Eye Dam. 1 (H318) STOT RE 2 (H373) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	23.2
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	Not Listed	*

SAFETY DATA SHEET

Material Name: Maropitant Citrate Tablets
Revision date: 12-Feb-2015

Page 3 of 10
Version: 5.2

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
FD&C Yellow No. 6; (Sunset yellow)	2783-94-0	220-491-7	Not Listed	Not Listed	*
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	Not Listed	*
Lactose	63-42-3	200-559-2	Not Listed	Not Listed	*

Additional Information:

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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:

Individuals with cardiac conditions may be more susceptible to toxicity in cases of overexposure.

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:

Formation of toxic gases is possible during heating or fire. 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. Dust can form an explosive mixture in air.

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 Tablets
Revision date: 12-Feb-2015

Page 4 of 10
Version: 5.2

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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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

Keep away from heat, sparks, flame and all other sources of ignition. When handling, use appropriate personal protective equipment (see Section 8). Minimize dust generation and accumulation. Avoid contact with eyes, skin and clothing. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames. Keep container tightly closed when not in use.

Specific end use(s): Veterinary product for the treatment of nausea and vomiting (antiemetic)

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/m³

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
Latvia OEL - TWA	2 mg/m ³
Vietnam OEL - TWAs	10 mg/m ³
	5 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Romania OEL - TWA	10 mg/m ³

SAFETY DATA SHEET

Material Name: Maropitant Citrate Tablets
Revision date: 12-Feb-2015

Page 5 of 10
Version: 5.2

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Spain OEL - TWA	10 mg/m ³
Switzerland OEL -TWAs	3 mg/m ³

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	5 mg/m ³

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section. General room ventilation is adequate unless the process generates dust, mist or fumes.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: 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

Physical State:	Tablet	Color:	Peach
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	No data available.
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)	
Maropitant citrate monohydrate	
Measured Log P	7.75
Decomposition Temperature (°C):	No data available.

Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	No data available
Vapor Density (g/ml):	No data available
Relative Density:	No data available
Viscosity:	No data available

Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

Polymerization: Will not occur

SAFETY DATA SHEET

Material Name: Maropitant Citrate Tablets
Revision date: 12-Feb-2015

Page 6 of 10
Version: 5.2

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been investigated. The information in this section describes the hazards of various forms of the active ingredient. The information in this section describes the potential hazards of the individual ingredients and the formulation.
Routes of exposure: eye contact , skin contact

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

Maropitant citrate monohydrate

Rat Dermal LDmin. > 2000 mg/kg

FD&C Yellow No. 6; (Sunset yellow)

Rat Oral LD50 > 10,000 mg/kg

Mouse Oral LD50 > 6,000mg/kg

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg

Rabbit Dermal LD50 > 2000 mg/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m³

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)

Maropitant citrate monohydrate

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Non-irritating

Skin Sensitization - GPMT Guinea Pig Negative

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Non-irritating

Irritation / Sensitization Comments: May cause irreversible eye damage.

SAFETY DATA SHEET

Material Name: Maropitant Citrate Tablets
Revision date: 12-Feb-2015

Page 7 of 10
Version: 5.2

11. TOXICOLOGICAL INFORMATION

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

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

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

Maropitant methanesulfonate salt

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vitro</i>	Human Lymphocytes	Negative
<i>In Vivo</i> Micronucleus	Mouse Bone Marrow	Negative
<i>In Vitro</i> 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.

FD&C Yellow No. 6; (Sunset yellow)

IARC: Group 3 (Not Classifiable)

SAFETY DATA SHEET

Material Name: Maropitant Citrate Tablets
Revision date: 12-Feb-2015

Page 8 of 10
Version: 5.2

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been investigated. Releases to the environment should be avoided. In the environment, the active ingredient in this formulation is expected to degrade slowly and may be harmful to aquatic organisms.

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	

Aquatic Toxicity Comments: The above aquatic toxicity studies were conducted with CJ-11,972 (free base). The effects of the two materials are predicted to be similar.

Persistence and Degradability: No data available

Bio-accumulative Potential:

Maropitant citrate monohydrate

Measured Log P 7.75

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Should not be released into the environment. 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

As of January 1, 2015, materials offered for transport that are classified for transportation only as Marine Pollutants and which are packaged in single or combination packagings containing a net quantity per single or inner packaging of 5 Liters or less for liquids or having a net mass per single or inner packaging of 5 kilograms or less for solids are NOT subject to ICAO/IATA, IMDG, or ADR transport regulations provided the general packaging requirements of those regulations are met. Refer to ICAO/IATA A197, IMDG 2.10.2.7, ADR SP 375.

UN number:	UN 3077
UN proper shipping name:	Environmentally Hazardous Substance, Solid, n.o.s (Maropitant citrate monohydrate)
Transport hazard class(es):	9
Packing group:	III

SAFETY DATA SHEET

Material Name: Maropitant Citrate Tablets
Revision date: 12-Feb-2015

Page 9 of 10
Version: 5.2

Environmental Hazard(s): Marine Pollutant

Please refer to the applicable dangerous goods regulations for additional information. Transport according to the requirements of the appropriate regulatory body.

DOT / ANTT: Not regulated for transportation

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

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.



Maropitant citrate monohydrate

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

FD&C Yellow No. 6; (Sunset yellow)

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	220-491-7

Croscarmellose sodium

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Microcrystalline cellulose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 9[f]. powder
EU EINECS/ELINCS List	232-674-9

SAFETY DATA SHEET

Material Name: Maropitant Citrate Tablets
Revision date: 12-Feb-2015

Page 10 of 10
Version: 5.2

15. REGULATORY INFORMATION

Magnesium stearate

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	209-150-3

Lactose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-559-2

16. OTHER INFORMATION

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

Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects

Xn - Harmful
Xi - Irritant
N - Dangerous for the environment

R41 - Risk of serious damage to eyes.
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 SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 11 - Toxicology Information. Updated Section 14 - Transport 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