

SAFETY DATA SHEET



Revision date: 21-Jan-2014

Version: 4.0

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

Product Identifier

Material Name: Cefovecin Sodium for Injection

Trade Name: CONVENIA
Chemical Family: Mixture

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

Intended Use: Veterinary product used as antibiotic agent
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: Off-white to yellow freeze-dried powder

Classification of the Substance or Mixture

GHS - Classification

Skin Sensitization: Category 1

EU Classification:

EU Indication of danger: Irritant

EU Symbol: Xi

EU Risk Phrases:
R43 - May cause sensitization by skin contact.

Label Elements

Signal Word: Warning
Hazard Statements: H317 - May cause an allergic skin reaction

Precautionary Statements: 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
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P321 - Specific treatment (see supplemental first aid instructions on this label)
P362 - Take off contaminated clothing and wash before reuse

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Other Hazards

Short Term:

Known Clinical Effects:

May cause skin irritation. May cause eye irritation (based on components) .
Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug. Additionally, kidney toxicity (nephrotoxicity) and Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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 | % |
|-------------------------|-------------|-----------------------|-------------------|--|----|
| Cefovecin sodium | 141195-77-9 | Not Listed | Xi; R43 | Skin Sens. 1, H317 | 20 |
| Sodium hydroxide | 1310-73-2 | 215-185-5 | C; R35 | Skin Corr. 1A (H314) | ** |
| Hydrochloric Acid | 7647-01-0 | 231-595-7 | T; R23 C; R35 | STOT SE 3 (H335) Skin Corr. 1A (H314) Press. Gas Acute Tox. 3 (H331) | ** |
| Citric acid monohydrate | 5949-29-1 | Not Listed | Not Listed | Not Listed | * |

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|---------------|------------|-----------------------|-------------------|--------------------|---|
| Methylparaben | 99-76-3 | 202-785-7 | Not Listed | Not Listed | * |
| Propylparaben | 94-13-3 | 202-307-7 | Not Listed | Not Listed | * |

Additional Information:

* Proprietary
** to adjust pH
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

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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. Delayed effects may occur. For information on potential delayed effects, see Section 2 - Hazards Identification and/or Section 11 - Toxicological Information. |
| 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: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

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.

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.

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7. HANDLING AND STORAGE

Precautions for Safe Handling

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

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: 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.

Cefovecin sodium

Zoetis OEL TWA 8-hr 1000 µg/m³, Sensitizer

Sodium hydroxide

| | |
|--------------------------------|-----------------------|
| ACGIH Ceiling Threshold Limit: | 2 mg/m ³ |
| Australia PEAK | 2 mg/m ³ |
| Austria OEL - MAKs | 2 mg/m ³ |
| Bulgaria OEL - TWA | 2.0 mg/m ³ |
| Czech Republic OEL - TWA | 1 mg/m ³ |
| Estonia OEL - TWA | 1 mg/m ³ |
| France OEL - TWA | 2 mg/m ³ |
| Greece OEL - TWA | 2 mg/m ³ |
| Hungary OEL - TWA | 2 mg/m ³ |
| Japan - OELs - Ceilings | 2 mg/m ³ |
| Latvia OEL - TWA | 0.5 mg/m ³ |
| OSHA - Final PELs - TWAs: | 2 mg/m ³ |
| Poland OEL - TWA | 0.5 mg/m ³ |
| Slovakia OEL - TWA | 2 mg/m ³ |
| Slovenia OEL - TWA | 2 mg/m ³ |
| Sweden OEL - TWAs | 1 mg/m ³ |
| Switzerland OEL - TWAs | 2 mg/m ³ |

Hydrochloric Acid

| | |
|--------------------------------|-----------------------|
| ACGIH Ceiling Threshold Limit: | 2 ppm |
| Australia PEAK | 5 ppm |
| | 7.5 mg/m ³ |
| Austria OEL - MAKs | 5 ppm |
| | 8 mg/m ³ |
| Belgium OEL - TWA | 5 ppm |
| | 8 mg/m ³ |
| Bulgaria OEL - TWA | 8.0 mg/m ³ |
| | 5 ppm |
| Cyprus OEL - TWA | 5 ppm |
| | 8 mg/m ³ |
| Czech Republic OEL - TWA | 8 mg/m ³ |

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|---------------------------|--------------------------------|
| Estonia OEL - TWA | 5 ppm 8 mg/m ³ |
| Germany - TRGS 900 - TWAs | 2 ppm 3 mg/m ³ |
| Germany (DFG) - MAK | 2 ppm 3.0 mg/m ³ |
| Greece OEL - TWA | 5 ppm 7 mg/m ³ |
| Hungary OEL - TWA | 8 mg/m ³ |
| Ireland OEL - TWAs | 5 ppm 8 mg/m ³ |
| Italy OEL - TWA | 5 ppm 8 mg/m ³ |
| Japan - OELs - Ceilings | 5 ppm 7.5 mg/m ³ |
| Latvia OEL - TWA | 5 ppm 8 mg/m ³ |
| Lithuania OEL - TWA | 5 ppm 8 mg/m ³ |
| Luxembourg OEL - TWA | 5 ppm 8 mg/m ³ |
| Malta OEL - TWA | 5 ppm 8 mg/m ³ |
| Netherlands OEL - TWA | 8 mg/m ³ |
| Vietnam OEL - TWAs | 5 mg/m ³ |
| Poland OEL - TWA | 5 mg/m ³ |
| Romania OEL - TWA | 5 ppm 8 mg/m ³ |
| Slovakia OEL - TWA | 5 ppm 8.0 mg/m ³ |
| Slovenia OEL - TWA | 5 ppm 8 mg/m ³ |
| Spain OEL - TWA | 5 ppm 7.6 mg/m ³ |
| Switzerland OEL - TWAs | 2 ppm 3.0 mg/m ³ |

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. Keep airborne contamination levels below the exposure limits listed above in this section.

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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|---|---------------------------|--------------------------|---------------------|
| Physical State: | Freeze-dried | Color: | Off-white to yellow |
| 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: | 6.2 - 7.5 (reconstituted) | | |
| Melting/Freezing Point (°C): | No data available | | |
| Boiling Point (°C): | No data available. | | |
| Partition Coefficient: (Method, pH, Endpoint, Value) | No data available | | |
| 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 | | |

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: | No data available |

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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

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

Propylparaben

Mouse Oral LD 50 6332 mg/kg
Mouse Sub-tenon injection (eye) LD 50 200 mg/kg

Sodium hydroxide

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11. TOXICOLOGICAL INFORMATION

Mouse IP LD50 40 mg/kg

Cefovecin sodium

Rat Oral LD50 >2000 mg/kg

Rat Dermal LD50 >2000 mg/kg

Dog Oral Maximally Tolerated Dose 1000 mg/kg

Dog Subcutaneous Maximally Tolerated Dose >2000 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)

Citric acid monohydrate

Eye Irritation Rabbit Mild

Skin Irritation Rabbit Mild

Sodium hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

Cefovecin sodium

Eye Irritation Rabbit Minimal

Skin Irritation Rabbit Non-irritating

Skin Sensitization - LLNA Mouse Positive

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

Propylparaben

3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system

4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

Cefovecin sodium

5 Week(s) Dog Subcutaneous 60 mg/kg/day NOAEL No effects at maximum dose

5 Week(s) Cat Subcutaneous 60 mg/kg/day NOAEL No effects at maximum dose

16 Week(s) Dog Subcutaneous 40 mg/kg/day NOAEL No effects at maximum dose

16 Week(s) Cat Subcutaneous 40 mg/kg/day NOAEL Gastrointestinal system

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

Cefovecin sodium

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

In Vivo Micronucleus Rat Bone Marrow Negative

Mammalian Cell Mutagenicity Mouse Lymphoma Equivocal without activation

Carcinogen Status:

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

Hydrochloric Acid

IARC:

Group 3 (Not Classifiable)

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12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity:

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

Cefovecin sodium

Daphnia magna (Water Flea) NPDES EC50 48 Hours > 1000 mg/L

Mysidopsis bahia (Mysid Shrimp) NPDES LC50 48 Hours 580 mg/L

Cyprinodon variegatus (Sheepshead Minnow) NPDES LC50 48 Hours 770 mg/L

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

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Cefovecin sodium

Polytox Surrogate IC50 10.31 mg/L

Polytox Surrogate MIC 1.85 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: 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.

15. REGULATORY INFORMATION

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

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15. REGULATORY INFORMATION

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision B



Cefovecin sodium

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

Methylparaben

| | |
|---|------------|
| 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 | 202-785-7 |

Propylparaben

| | |
|---|------------|
| 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 | 202-307-7 |

Sodium hydroxide

| | |
|---|--------------------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| CERCLA/SARA Hazardous Substances and their Reportable Quantities: | 1000 lb 454 kg |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 5 Schedule 6 |
| EU EINECS/ELINCS List | 215-185-5 |

Hydrochloric Acid

| | |
|--|--------------------|
| CERCLA/SARA 313 Emission reporting | 1.0 % |
| CERCLA/SARA Hazardous Substances and their Reportable Quantities: | 5000 lb 2270 kg |
| CERCLA/SARA - Section 302 Extremely Hazardous TPQs | 500 lb |
| CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs | 5000 lb |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |

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15. REGULATORY INFORMATION

| | |
|---|------------|
| Australia (AICS): | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 5 |
| EU EINECS/ELINCS List | Schedule 6 |
| | 231-595-7 |

Citric acid monohydrate

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

REACH Authorizations: 4.0

16. OTHER INFORMATION

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

H314 - Causes severe skin burns and eye damage
H317 - May cause an allergic skin reaction
H331 - Toxic if inhaled
H335 - May cause respiratory irritation

R23 - Toxic by inhalation.
R35 - Causes severe burns.
R43 - May cause sensitization by skin contact.

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 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Material 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