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
- Zoetis Belgium S.A.
  Mercuriusstraat 20
  1930 Zaventem
  Belgium
  Product Support/Technical Services Phone: 1-800-366-5288

Emergency telephone number:
- CHEMTREC (24 hours): 1-800-424-9300
- VMIPSprecords@zoetis.com

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
Other Hazards

Short Term:

May cause skin irritation. May cause eye irritation (based on components).

Known Clinical Effects:

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.

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

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cefovecin sodium</td>
<td>141195-77-9</td>
<td>Not Listed</td>
<td>Xi;R43</td>
<td>Skin Sens. 1,H317</td>
<td>20</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>C; R35</td>
<td>Skin Corr. 1A (H314)</td>
<td>**</td>
</tr>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>T; R23</td>
<td>STOT SE 3 (H335)</td>
<td>**</td>
</tr>
<tr>
<td>Citric acid monohydrate</td>
<td>5949-29-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Propylparaben</td>
<td>94-13-3</td>
<td>202-307-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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
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.
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/m³
Australia PEAK 2 mg/m³
Austria OEL - MAKs 2 mg/m³
Bulgaria OEL - TWA 2.0 mg/m³
Czech Republic OEL - TWA 1 mg/m³
Estonia OEL - TWA 1 mg/m³
France OEL - TWA 2 mg/m³
Greece OEL - TWA 2 mg/m³
Hungary OEL - TWA 2 mg/m³
Japan - OELs - Ceilings 2 mg/m³
Latvia OEL - TWA 0.5 mg/m³
OSHA - Final PELS - TWAs: 2 mg/m³
Poland OEL - TWA 0.5 mg/m³
Slovakia OEL - TWA 2 mg/m³
Slovenia OEL - TWA 2 mg/m³
Sweden OEL - TWAs 1 mg/m³
Switzerland OEL -TWAs 2 mg/m³

Hydrochloric Acid
ACGIH Ceiling Threshold Limit: 2 ppm
Australia PEAK 5 ppm
Austria OEL - MAKs 5 ppm
Belgium OEL - TWA 5 ppm
Bulgaria OEL - TWA 8.0 mg/m³
Cyprus OEL - TWA 5 ppm
Czech Republic OEL - TWA 8 mg/m³
## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country/Organization</th>
<th>Exposure Limit</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estonia OEL - TWA</td>
<td>5 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>2 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>2 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3.0 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>5 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>5 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Italy OEL - TWA</td>
<td>5 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>5 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7.5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>5 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Luxembourg OEL - TWA</td>
<td>5 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Malta OEL - TWA</td>
<td>5 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>5 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>5 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8.0 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>5 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>5 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7.6 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>2 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3.0 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

**Exposure 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.
9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Freeze-dried
Odor: No data available.
Molecular Formula: 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

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
11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Material Name: Cefovecin Sodium for Injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision date: 21-Jan-2014</td>
</tr>
<tr>
<td>Page 7 of 10</td>
</tr>
<tr>
<td>Version: 4.0</td>
</tr>
</tbody>
</table>

**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)**

**Cefovecin sodium**

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 Week(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>347.2 mg/kg</td>
<td>LOAEL</td>
<td>Male reproductive system</td>
</tr>
</tbody>
</table>

**Glutaric Acid**

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>NOAEL</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 Week(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>27.1 g/kg</td>
<td>Endocrine system</td>
<td></td>
</tr>
<tr>
<td>4 Week(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>347.2 mg/kg</td>
<td>Male reproductive system</td>
<td></td>
</tr>
</tbody>
</table>

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

**Cefovecin sodium**

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 Week(s)</td>
<td>Dog</td>
<td>Subcutaneous</td>
<td>60 mg/kg/day</td>
<td>NOAEL</td>
<td>No effects at maximum dose</td>
</tr>
<tr>
<td>5 Week(s)</td>
<td>Cat</td>
<td>Subcutaneous</td>
<td>60 mg/kg/day</td>
<td>NOAEL</td>
<td>No effects at maximum dose</td>
</tr>
<tr>
<td>16 Week(s)</td>
<td>Dog</td>
<td>Subcutaneous</td>
<td>40 mg/kg/day</td>
<td>NOAEL</td>
<td>No effects at maximum dose</td>
</tr>
<tr>
<td>16 Week(s)</td>
<td>Cat</td>
<td>Subcutaneous</td>
<td>40 mg/kg/day</td>
<td>NOAEL</td>
<td>Gastrointestinal system</td>
</tr>
</tbody>
</table>

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

**Cefovecin sodium**

<table>
<thead>
<tr>
<th>Method</th>
<th>Organism</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial Mutagenicity (Ames)</td>
<td>Salmonella, E. coli</td>
<td>Negative</td>
</tr>
<tr>
<td>In Vivo Micronucleus</td>
<td>Rat Bone Marrow</td>
<td>Negative</td>
</tr>
<tr>
<td>Mammalian Cell Mutagenicity</td>
<td>Mouse Lymphoma</td>
<td>Equivocal without activation</td>
</tr>
</tbody>
</table>

**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)
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
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
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 TPOs 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
15. REGULATORY INFORMATION

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