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

Pfizer Animal Health
Pfizer Inc
235 East 42nd Street
New York, NY 10017

Pfizer Ltd, Kent
CT13 9NJ
United Kingdom

Poison Control Center Phone: 1-866-531-8896
Technical Services Phone: 1-800-366-5288

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Emergency telephone number:
ChemSafe (24 hours): +00 44 (0)1304 616161

Contact E-Mail: pfizer-MSDS@pfizer.com

Material Name: Cefovecin Sodium for Injection

Trade Name: CONVENIA
Chemical Family: Mixture
Intended Use: Veterinary product used as antibiotic agent
Restrictions on Use: Not for human use

2. HAZARDS IDENTIFICATION

Appearance: Off-white to yellow freeze-dried powder
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.

Additional Hazard Information:

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.

EU Indication of danger: Irritant

EU Hazard Symbols:

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


Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>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>20</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>C;R35</td>
<td>**</td>
</tr>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>C;R35;T;R23</td>
<td>**</td>
</tr>
<tr>
<td>Citric acid monohydrate</td>
<td>5949-29-1</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>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium citrate, dihydrate</td>
<td>6132-04-3</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</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>*</td>
</tr>
<tr>
<td>Water for injection</td>
<td>7732-18-5</td>
<td>231-791-2</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 mentioned in this Section, see Section 16

4. 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.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: No data available

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: No data available

6. ACCIDENTAL RELEASE MEASURES
Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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.

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

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

General Handling: Minimize dust generation and accumulation. Avoid breathing dust. 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Cefovecin sodium
Pfizer OEL TWA-8 Hr: 1000µg/m³, Sensitizer

Sodium hydroxide
ACGIH Ceiling Threshold Limit: = 2 mg/m³ Ceiling
Australia PEAK = 2 mg/m³ Peak
Austria OEL - MAKs = 2 mg/m³ MAK
Belgium OEL - TWA = 2 mg/m³ TWA
Bulgaria OEL - TWA = 2.0 mg/m³ TWA
Czech Republic OEL - TWA = 1 mg/m³ TWA
Finland OEL - TWA = 2 mg/m³ TWA
France OEL - TWA = 2 mg/m³ VME
Greece OEL - TWA = 2 mg/m³ TWA
Hungary OEL - TWA = 2 mg/m³ TWA
Latvia OEL - TWA = 0.5 mg/m³ TWA
OSHA - Final PELS - TWA: = 2 mg/m³
Poland OEL - TWA = 0.5 mg/m³ NDS
Slovakia OEL - TWA = 2 mg/m³ TWA
Slovenia OEL - TWA = 2 mg/m³ TWA
Sweden OEL - TWA= 1 mg/m³ LLV

Hydrochloric Acid
ACGIH Ceiling Threshold Limit: = 2 ppm Ceiling
Australia PEAK = 5 ppm Peak
= 7.5 mg/m³ Peak
Austria OEL - MAKs = 5 ppm MAK
= 8 mg/m³ MAK
Belgium OEL - TWA = 5 ppm TWA
= 8 mg/m³ TWA
Bulgaria OEL - TWA = 8.0 mg/m³ TWA
The exposure limit(s) listed for solid components are only relevant if dust may be generated.


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:

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  
Color: Off-white to yellow  
Molecular Formula: Mixture  
Molecular Weight: Mixture  

pH: 6.2 - 7.5 (reconstituted)

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.  
Conditions to Avoid: No data available  
Incompatible Materials: No data available

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)  
Methylparaben  
Mouse Oral LD50 > 8000 mg/kg  
Rat Oral LD50 2280 mg/kg  

Propylparaben  
Mouse Oral LD50 6332 mg/kg  
Mouse Intraperitoneal LD 50 200 mg/kg  

Sodium hydroxide  
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)

<table>
<thead>
<tr>
<th>Compound</th>
<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>Propylparaben</td>
<td>3 Week(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>27.1 g/kg</td>
<td>LOAEL</td>
<td>Endocrine system</td>
</tr>
<tr>
<td></td>
<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>
<tr>
<td>Cefovecin sodium</td>
<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></td>
<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></td>
<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></td>
<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)

<table>
<thead>
<tr>
<th>Compound</th>
<th>Study Type</th>
<th>Cell Type/Organism</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cefovecin sodium</td>
<td>In Vivo</td>
<td>Micronucleus</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>In Vivo</td>
<td>Rat Bone Marrow</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Mammalian</td>
<td>Cell Mutagenicity</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

### 12. ECOLOGICAL INFORMATION

#### Environmental Overview:

The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided. See Aquatic toxicity data of the active ingredient, below:

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

<table>
<thead>
<tr>
<th>Compound</th>
<th>Species</th>
<th>Method</th>
<th>End Point</th>
<th>Duration</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cefovecin sodium</td>
<td><em>Daphnia magna</em> (Water Flea)</td>
<td>NPDES</td>
<td>EC50</td>
<td>48 Hours</td>
<td>&gt; 1000 mg/L</td>
</tr>
<tr>
<td></td>
<td><em>Mysisopsis bahia</em> (Mysid Shrimp)</td>
<td>NPDES</td>
<td>LC50</td>
<td>48 Hours</td>
<td>580 mg/L</td>
</tr>
<tr>
<td></td>
<td><em>Cyprinodon variegatus</em> (Sheepshead Minnow)</td>
<td>NPDES</td>
<td>LC50</td>
<td>48 Hours</td>
<td>770 mg/L</td>
</tr>
</tbody>
</table>

#### Aquatic Toxicity Comments:

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

#### Bacterial Inhibition: (Species, Method, End Point, Duration, Result)

<table>
<thead>
<tr>
<th>Compound</th>
<th>Species</th>
<th>Method</th>
<th>End Point</th>
<th>Duration</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cefovecin sodium</td>
<td>Polytox</td>
<td>Surrogate</td>
<td>IC50</td>
<td>4 Hours</td>
<td>10.31 mg/L</td>
</tr>
<tr>
<td></td>
<td>Polytox</td>
<td>Surrogate</td>
<td>MIC</td>
<td>4 Hours</td>
<td>1.85 mg/L</td>
</tr>
</tbody>
</table>
13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: Xi
EU Indication of danger: Irritant
EU Risk Phrases: R43 - May cause sensitization by skin contact.
EU Safety Phrases: S24 - Avoid contact with skin. S37 - Wear suitable gloves.

OSHA Label: WARNING
May cause allergic skin reaction.

Canada - WHMIS: Classifications
WHMIS hazard class: D2b  toxic materials

Sodium citrate, dihydrate
  Australia (AICS): Present
  Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 5
  Schedule 6

Methylparaben
  Inventory - United States TSCA - Sect. 8(b): Present
  Australia (AICS): Present
  EU EINECS/ELINCS List: 202-785-7
16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

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

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 12 - Ecological Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety
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End of Safety Data Sheet