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

Material Name: Lincomycin Hydrochloride Injection, USP

Trade Name: Lincocin® Injection
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: Liquid

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information: Short Term: May cause eye, skin and respiratory tract irritation. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

Known Clinical Effects: The most common adverse effects reported with clinical use were diarrhea, nausea, rash, and vomiting. Effects on blood and blood-forming organs have also occurred. This compound can cross the placenta in pregnant women. Secreted in human breast milk.

EU Indication of danger: Not classified


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>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lincomycin Hydrochloride</td>
<td>859-18-7</td>
<td>212-726-7</td>
<td>Xi;R43</td>
<td>0.5</td>
</tr>
</tbody>
</table>

PZ01161
### 4. FIRST AID MEASURES

<table>
<thead>
<tr>
<th>Condition</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Contact</td>
<td>Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.</td>
</tr>
<tr>
<td>Skin Contact</td>
<td>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.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>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.</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Remove to fresh air and keep patient at rest. Seek medical attention immediately.</td>
</tr>
</tbody>
</table>

### 5. FIRE FIGHTING MEASURES

<table>
<thead>
<tr>
<th>Component</th>
<th>Extinguishing Media</th>
<th>Hazardous Combustion Products</th>
<th>Fire Fighting Procedures</th>
<th>Fire / Explosion Hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Use carbon dioxide, dry chemical, or water spray.</td>
<td>Not determined</td>
<td>During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

### 6. ACCIDENTAL RELEASE MEASURES

<table>
<thead>
<tr>
<th>Condition</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health and Safety Precautions</td>
<td>Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.</td>
</tr>
<tr>
<td>Measures for Cleaning / Collecting</td>
<td>Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.</td>
</tr>
<tr>
<td>Measures for Environmental Protections</td>
<td>Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.</td>
</tr>
<tr>
<td>Additional Consideration for Large Spills</td>
<td>Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.</td>
</tr>
</tbody>
</table>


7. HANDLING AND STORAGE

General Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). 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.

Storage Conditions: Store in a cool, dry place away from light. Keep out of reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Benzyl Alcohol
- Bulgaria OEL - TWA: Listed
- Czech Republic OEL - TWA: Listed
- Latvia OEL - TWA: Listed
- Lithuania OEL - TWA: Listed
- Poland OEL - TWA: Listed

Lincomycin Hydrochloride
- Pfizer OEL TWA-8 Hr: 100 µg/m³

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated. Refer to available public information for specific member state Occupational Exposure Limits.

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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

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: Liquid
- Molecular Formula: Mixture
- Color: No data available.
- Molecular Weight: Mixture
- Solubility: Soluble: Water

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
10. STABILITY AND REACTIVITY

Conditions to Avoid: Not determined
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)

Lincomycin Hydrochloride
Rat Oral LD 50 > 4000 mg/kg
Rat Para-periosteal LD 50 342 mg/kg
Mouse Intravenous LD 50 214 mg/kg
Rat Subcutaneous LD 50 9778 mg/kg

Benzyl Alcohol
Rat Oral LD50 1230 mg/kg
Rat Para-periosteal LD50 53 mg/kg
Rat Inhalation LC50 46 mg/m³

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)

Benzyl Alcohol
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Moderate
Skin Irritation Guinea Pig Moderate

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

Lincomycin Hydrochloride
30 Day(s) Rat Oral 300 mg/kg/day NOAEL No effects at maximum dose
30 Day(s) Rat Subcutaneous 60 mg/kg/day NOAEL None identified
3 Month(s) Rat Oral 300 mg/kg/day NOAEL None identified
3 Month(s) Dog Oral 400 mg/kg/day LOAEL None identified
6 Month(s) Dog Oral 100 mg/kg/day NOAEL Immune system

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

Lincomycin Hydrochloride
2 Generation Reproductive Toxicity Rat Oral 100 mg/kg LOAEL Fetotoxicity
Prenatal & Postnatal Development Rat Oral 100 mg/kg NOEL Not Teratogenic
Fertility and Embryonic Development Rat Subcutaneous 75 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rat Subcutaneous 300 mg/kg/day NOAEL Not Teratogenic
Peri-/Postnatal Development Rat Subcutaneous 30 mg/kg/day NOAEL No effects at maximum dose

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

Lincomycin Hydrochloride
Bacterial Mutagenicity (Ames) Salmonella Negative
Mammalian Cell Mutagenicity Mouse Lymphoma Negative
11. TOXICOLOGICAL INFORMATION

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

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided. See aquatic toxicity data for individual components below.

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>End Point</th>
<th>Duration</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmo gairdneri (Trout)</td>
<td>ASTM</td>
<td>LC50</td>
<td>96 Hours</td>
<td>&gt;980 mg/L</td>
</tr>
<tr>
<td>Daphnia magna (Water Flea)</td>
<td>ASTM</td>
<td>EC50</td>
<td>48 Hours</td>
<td>&gt;900 mg/L</td>
</tr>
<tr>
<td>Anabaena flos-aquae (Cyanobacteria)</td>
<td>OECD</td>
<td>EC50</td>
<td>72 Hours</td>
<td>0.03 mg/L</td>
</tr>
<tr>
<td>Lepomis macrochirus (Bluegill Sunfish)</td>
<td>ASTM</td>
<td>LC50</td>
<td>96 Hours</td>
<td>&gt;980 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.

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

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

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label: Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications
15. REGULATORY INFORMATION

WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.
(Bad file name or number)

Benzyl Alcohol
- Inventory - United States TSCA - Sect. 8(b): Listed
- Australia (AICS): Listed
- EU EINECS/ELINCS List: 202-859-9

Lincomycin Hydrochloride
- Australia (AICS): Listed
- EU EINECS/ELINCS List: 212-726-7

Water
- Inventory - United States TSCA - Sect. 8(b): Listed
- Australia (AICS): Listed
- REACH - Annex IV - Exemptions from the obligations of Register: Present
- EU EINECS/ELINCS List: 231-791-2

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3
R43 - May cause sensitization by skin contact.
R20/22 - Harmful by inhalation and if swallowed.

Data Sources: Safety data sheets for individual ingredients. Publicly available toxicity information.
Reasons for Revision: Not applicable
Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer 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