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

Product Identifier

Material Name: Lincomycin Hydrochloride Injection, USP
Trade Name: Lincocin® Injection; LINCOCINE; FRADEMICINA
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
Intended Use: Pharmaceutical product used as antibiotic agent

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture
GHS - Classification Not classified as hazardous

Label Elements
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards
An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
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PZ01161
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<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>Acute Tox.4 (H302)</td>
<td>&lt;5</td>
</tr>
<tr>
<td>Lincomycin Hydrochloride</td>
<td>859-18-7</td>
<td>212-726-7</td>
<td>Skin Sens.1 (H317)</td>
<td>0.5</td>
</tr>
</tbody>
</table>

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 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 mists) may fuel fires/explosions.

Advice for Fire-Fighters
During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
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 spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe 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.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store in a cool, dry place away from light. Keep out of reach of children.
Specific end use(s): Pharmaceutical product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Benzyl Alcohol
- Bulgaria OEL - TWA: 5.0 mg/m³
- Czech Republic OEL - TWA: 40 mg/m³
- Finland OEL - TWA: 10 ppm
- Latvia OEL - TWA: 45 mg/m³
- Lithuania OEL - TWA: 5 mg/m³
- Poland OEL - TWA: 240 mg/m³

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

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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Hands:** Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

**Eyes:** Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

**Respiratory protection:** Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Liquid

**Odor:** No data available.

**Molecular Formula:** Mixture

**Solvent Solubility:** No data available

**Water Solubility:** No data available

**Solubility:** Soluble: Water

**pH:** No data available.

**Melting/Freezing Point (°C):** No data available

**Boiling Point (°C):** No data available

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**Water**

**Lincomycin Hydrochloride**

Measured 6-8 Log D 2.55

**Non-hazardous Ingredients**

No data available

**Benzyl Alcohol**

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.
10. STABILITY AND REACTIVITY

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

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.

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.

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

Lincomycin Hydrochloride
- Rat Oral LD50 > 4000 mg/kg
- Rat Para-periosteal LD50 342mg/kg
- Mouse Intravenous LD50 214mg/kg
- Rat Subcutaneous LD50 9778mg/kg

Benzyl Alcohol
- Rat Oral LD50 1230 mg/kg
- Rat Para-periosteal LD50 53mg/kg
- Rat Inhalation LC50 > 4.178mg/L

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 Minimal
- 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
11. TOXICOLOGICAL INFORMATION

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
In Vivo Micronucleus Rat Negative
Direct DNA Interaction Human Lymphocytes Negative

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.

Toxicity:

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

Lincomycin Hydrochloride
Lepomis macrochirus (Bluegill Sunfish) ASTM LC50 96 Hours >980 mg/L
Daphnia magna (Water Flea) ASTM EC50 48 Hours >900 mg/L
Anabaena flos-aquae (Cyanobacteria) OECD EC50 72 Hours 0.03 mg/L
Salmo gairdneri (Trout) ASTM LC50 96 Hours >980 mg/L

Benzyl Alcohol
Pimephales promelas (Fathead Minnow) EPA LC50 96 Hours 460 mg/L
Daphnia magna (Water Flea) OECD EC50 48 Hours 230 mg/L
Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 Hours 500 mg/L

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

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Benzyl Alcohol
Daphnia magna (Water Flea) OECD 21 Day(s) EC50 66 mg/L Reproduction

Persistence and Degradability:

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

Benzyl Alcohol
OECD Activated sludge Ready 92% After 14 Day(s) Ready
Bio-accumulative Potential:  
Partition Coefficient: (Method, pH, Endpoint, Value)  
Lincomycin Hydrochloride  
Measured  6-8  Log D  2.55

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

**Benzyl Alcohol**
- 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: 202-859-9

**Lincomycin Hydrochloride**
- CERCLA/SARA 313 Emission reporting: Not Listed  
- California Proposition 65: Not Listed  
- Australia (AICS): Present  
- EU EINECS/ELINCS List: 212-726-7

**Water**
- CERCLA/SARA 313 Emission reporting: Not Listed
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>California Proposition 65</th>
<th>Not Listed</th>
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<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
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<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>REACH - Annex IV - Exemptions from the obligations of Register:</td>
<td>Present</td>
</tr>
</tbody>
</table>

EU EINECS/ELINCS List: 231-791-2

REACH Authorizations: 3.1

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

- Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction
- Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
- Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled

Data Sources: Safety data sheets for individual ingredients. Publicly available toxicity information.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 09-Aug-2018

Prepared by: Product Stewardship Hazard Communication

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