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

Material Name: Lincomycin Hydrochloride Liquid

Trade Name: Lincocin Aquadrops®
Chemical Family: Mixture
Intended Use: Veterinary product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless solution

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>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lincomycin Hydrochloride</td>
<td>859-18-7</td>
<td>212-726-7</td>
<td>Xn; R43</td>
<td>0.25</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</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sorbic acid</td>
<td>110-44-1</td>
<td>203-768-7</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
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: Not determined

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

Fire / Explosion Hazards: Not applicable

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 spill with absorbent material. 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: 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.

Storage Conditions: Store as directed by product packaging. Keep out of reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

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: Liquid

Color: Colorless

Molecular Formula: Mixture

Molecular Weight: Mixture

Solubility: Soluble: Water

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.

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)
Methylparaben
Mouse  Oral  LD50  > 8000 mg/kg
Rat   Oral  LD50  2280 mg/kg

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

Sorbit acid
Rat  Oral  LD50  7360 mg/kg
Mouse  Oral  LD50  3200 mg/kg

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

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

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
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:

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

Lincomycin Hydrochloride

*Salmo gairdneri* (Trout)  
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 30.5 ug/L

*Salmo gairdneri* (Trout)  
ASTM LC50 96 Hours >980 mg/L

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

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 Indication of danger: Not classified

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

Canada - WHMIS: Classifications

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.
16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R43 - May cause sensitization by skin contact.

Data Sources: Safety data sheets for individual ingredients. 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

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