Section 1 - Identification of the Material and Supplier

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Fax: (02) 8876 0444
Email: australia.animalhealth@zoetis.com

Chemical nature: Lincomycin is an antibiotic

Trade Name: Lincomix Antibiotic Solution 300mg/mL

Product Use: Antibiotic injection for the treatment of infections caused by micro-organisms sensitive to lincomycin

Creation Date: January, 2005

This version issued: 1 October, 2016 and is valid for 5 years from this date

Section 2 - Hazards Identification

Appearance: Colorless liquid

Classification of the Substance or Mixture

GHS - Classification
Skin Sensitization: Category 1

Label Elements

Signal Word: Warning

Hazard Statements: H317 - May cause an allergic skin reaction

Precautionary Statements:
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P272 - Contaminated work clothing should not be allowed out of the workplace
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P362 - Take off contaminated clothing and wash before reuse
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards

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. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

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

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.

Section 3 - Composition/Information on Ingredients

<table>
<thead>
<tr>
<th>Hazardous Ingredients</th>
<th>CAS No</th>
<th>Conc,%</th>
<th>GHS Classification</th>
</tr>
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<tbody>
<tr>
<td>Lincomycin Hydrochloride</td>
<td>859-18-7</td>
<td>2.5 – 30</td>
<td>Skin Sens.1 (H317)</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>1</td>
<td>Acute Tox.4 (H302)</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>*</td>
<td>Not Listed</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.

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non-hazardous ingredients are also possible.

Section 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.

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: Individuals with a history of hypersensitivity to this material or other materials in its chemical class, individuals with other allergic conditions or diseases (asthma, eczema, etc.).

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None
Section 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: Formation of toxic gases is possible during heating or fire.

Products:

Fire / Explosion Hazards: Not flammable.

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Additional Information: This product is a nonflammable aqueous solution.

Section 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 Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Large Spills:

Large Spills: Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Section 7 - Handling and Storage

Precautions for Safe Handling

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

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Keep in tightly sealed containers in a well-ventilated area away from heat and sources of ignition. Store as directed by product packaging.

Specific end use(s): No data available
Section 8 - Exposure Controls and Personal Protection

Control Parameters

Lincomycin Hydrochloride

Zoetis OEL TWA 8-hr 100μg/m³

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section. General room ventilation is adequate unless the process generates dust, mist or fumes.

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.

Section 9 - Physical and Chemical Properties:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Liquid</th>
<th>Color:</th>
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<tr>
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<td>Mixture</td>
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<td>Melting/Freezing Point (°C):</td>
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<td>Boiling Point (°C):</td>
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<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
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<td></td>
</tr>
</tbody>
</table>

Lincomycin Hydrochloride

Measured 6-8 Log D 2.55

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
Section 10 - Stability and Reactivity

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use

Possibility of Hazardous Reactions

Oxidizing Properties: None
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: Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

Section 11 - Toxicological Information

Information on Toxicological Effects

General Information:
Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation. Routes of exposure: eye contact, skin contact

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.

Inhalation Acute Toxicity
Allergic reactions might occur based on effects of the individual components.

Irritation / Sensitization: (Study Type, Species, Severity)

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

Irritation / Sensitization Comments: May cause eye irritation based on components.
Skin Irritation / Sensitization Comments: May cause skin irritation based on components. May cause allergic reactions in susceptible individuals.

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  Fetal toxicity
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.

Section 12 - Ecological Information

Environmental Overview:  Environmental properties of the formulation have not been 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  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:
Benzyl Alcohol
OECD  Activated sludge  Ready  92% After  14 Day(s)  Ready

Bio-accumulative Potential:
Lincomycin Hydrochloride
Measured  6-8  Log D  2.55

Mobility in Soil:  No data available
Section 13 - Disposal Considerations

**Disposal:** Dispose of empty container by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled sharps container.

Section 14 - Transport Information

The following refers to all modes of transportation unless specified below.
Not regulated for transport under IATA, ADG or IMDG regulations

Section 15 - Regulatory Information

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

**Poison Schedule:** Schedule 4

**Lincomycin Hydrochloride**
Australia (AICS): Present

**Benzyl Alcohol**
Australia (AICS): Present

**Water**
Australia (AICS): Present

**AICS:** All of the significant ingredients in this formulation are compliant with NICNAS regulations.
The following ingredient: Lincomycin is mentioned in the SUSMP.

Section 16 - Other Information

This MSDS contains only safety-related information. For other data see product literature.

**Acronyms:**

- AICS: Australian Inventory of Chemical Substances
- CAS number: Chemical Abstracts Service Registry Number
- Hazchem Number: Emergency action code of numbers and letters that provide information to emergency services especially firefighters
- IARC: International Agency for Research on Cancer
- SWA: Safe Work Australia, formerly ASCC and NOHSC
- NOS: Not otherwise specified
- NTP: National Toxicology Program (USA)
- R-Phrase: Risk Phrase
- SUSMP: Standard for the Uniform Scheduling of Medicines & Poisons
- UN Number: United Nations Number

**This version issued:** 1 October 2016 and is valid for 5 years from this date

**Supersedes:** Revision issued July 2016

**Revision History:**

<table>
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<tr>
<th>Date of Revision</th>
<th>Reason</th>
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<tbody>
<tr>
<td>17 Nov 2014</td>
<td>Update to GHS</td>
</tr>
<tr>
<td>01 Jul 2016</td>
<td>Revision for consistency with Zoetis organisation</td>
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</tbody>
</table>
This SDS summarises our current and best knowledge of the health and safety hazard information about the product detailed in this SDS, and how to safely handle and use the product in the workplace for the recommended use. Each user of the product must review this SDS in the context of how the product will be handled and used in their own workplace. If clarification or further information is needed to ensure that an appropriate risk assessment can be made, the user should contact Zoetis.

Please read all labels carefully before using product.

This SDS is prepared in accord with the SWA document “Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice” (December 2011)

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