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

<table>
<thead>
<tr>
<th>Product Identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material Name: Lincomycin Hydrochloride/Spectinomycin Sulfate Tetrahydrate (50) Water Soluble Powder</td>
</tr>
<tr>
<td>Trade Name: L-S 50 Water Soluble Powder</td>
</tr>
<tr>
<td>Synonyms: Linco-Spectin; Linco-Spectin 50</td>
</tr>
<tr>
<td>Chemical Family: Mixture</td>
</tr>
</tbody>
</table>

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

- **Intended Use:** Veterinary product used as antibiotic agent
- **Restrictions on Use:** Not for human use

## 2. HAZARDS IDENTIFICATION

### Appearance:
White powder

### Classification of the Substance or Mixture

#### GHS - Classification
- Skin Sensitization: Category 1

#### US OSHA Specific - Classification
- **Physical Hazard:** Combustible Dust

#### EU Classification:
- **EU Indication of danger:** Irritant
- **EU Symbol:** Xi
- **EU Risk Phrases:** R43 - May cause sensitization by skin contact.

### Label Elements

- **Signal Word:** Warning
- **Hazard Statements:** H317 - May cause an allergic skin reaction
  May form combustible dust concentrations in air
Material Name: Lincomycin Hydrochloride/Spectinomycin Sulfate Tetrahydrate (50) Water Soluble Powder
Revision date: 22-Feb-2014

Precautionary Statements:

P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P272 - Contaminated work clothing should not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P302+P352 - IF ON SKIN: Wash with plenty of soap and water
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention
P362 - Take off contaminated clothing and wash before reuse
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards

Short Term: May cause eye irritation, May cause skin irritation. (based on components). Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

Known Clinical Effects: The most common adverse effects seen during clinical use of this drug include nausea, fever, vomiting, diarrhea, skin rash. Effects on blood and blood-forming organs 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.

### 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>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spectinomycin Sulfate Tetrahydrate</td>
<td>64058-48-6</td>
<td>Not Listed</td>
<td>Xi;R43</td>
<td>Skin Sens. 1</td>
<td>44</td>
</tr>
<tr>
<td>Lincomycin Hydrochloride</td>
<td>859-18-7</td>
<td>212-726-7</td>
<td>Xi;R43</td>
<td>Skin Sens. 1</td>
<td>22</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>Not Listed</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 and CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

Description of First Aid Measures
### 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. |
| **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:**
Breathing dust may worsen asthma symptoms.

**Indication of the Immediate Medical Attention and Special Treatment Needed**
None

### 5. FIRE-FIGHTING MEASURES

| **Extinguishing Media:** | Extinguish fires with CO2, extinguishing powder, foam, or water. |
| **Hazardous Combustion Products:** | Formation of toxic gases is possible during heating or fire. |
| **Fire / Explosion Hazards:** | Dust can form an explosive mixture in air. |

**Advice for Fire-Fighters**
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

| **Personal Precautions, Protective Equipment and Emergency Procedures** |
| Avoid dust formation. 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** |
| Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Collect spilled material by a method that controls dust generation. Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. |

| **Additional Consideration for Large Spills:** |
| Avoid generating airborne dust. Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Collect spill with an inert, non-combustible absorbent material and transfer to labeled container for disposal. |
7. HANDLING AND STORAGE

Precautions for Safe Handling
Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Minimize dust generation and accumulation. Use with adequate ventilation. When handling, use appropriate personal protective equipment (see Section 8). 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: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.
Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Spectinomycin Sulfate Tetrahydrate
Zoetis OEL TWA 8-hr 2000µg/m³
Lincomycin Hydrochloride
Zoetis OEL TWA 8-hr 100µg/m³
Sucrose
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 10 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 6 mg/m³
Spain OEL - TWA 10 mg/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).

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.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Powder</td>
</tr>
<tr>
<td>Odor</td>
<td>Slight</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble: Water</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>No data available</td>
</tr>
<tr>
<td>Spectinomycin Sulfate Tetrahydrate</td>
<td>Measured 7.4 Log D -2.44</td>
</tr>
<tr>
<td>Lincomycin Hydrochloride</td>
<td>Measured 6-8 Log D 2.55</td>
</tr>
<tr>
<td>Decomposition Temperature (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (kPa)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (g/ml)</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability</td>
<td></td>
</tr>
<tr>
<td>Autoignition Temperature (Solid) (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (Solids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash Point (Liquid) (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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: Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electrostatic discharge). Dust may form explosive mixture in air.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: Hazardous combustion products may include oxides of carbon

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
11. TOXICOLOGICAL INFORMATION

General Information: Toxico logical properties of the formulation have not been investigated. The information included in this section describes the potential hazards of the individual ingredients.

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

Spectinomycin Sulfate Tetrahydrate
- Rat Oral LD 50 >5000 mg/kg
- Mouse Sub-tenon injection (eye) LD 50 3577mg/kg
- Mouse Intravenous LD 50 1022mg/kg

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

Sucrose
- Rat Oral LD 50 29.7 g/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)

Spectinomycin Sulfate Tetrahydrate
- Skin Irritation Rabbit No effect
- Eye Irritation Rabbit Minimal

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

Spectinomycin Sulfate Tetrahydrate
- 13 Week(s) Rat Oral 400 mg/kg/day NOAEL None identified
- 13 Week(s) Rat Oral 3000 mg/kg/day LOAEL None identified
- 90 Day(s) Dog Oral 50 mg/kg/day NOAEL None identified

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))

Spectinomycin Sulfate Tetrahydrate
- Reproductive & Fertility Rat Oral 400 mg/kg/day NOEL Maternal toxicity, Paternal toxicity, Fetotoxicity
- Reproductive & Fertility Rat Oral 2000 mg/kg/day NOAEL Maternal Toxicity, Paternal toxicity, Fetotoxicity

Embryo / Fetal Development
- Rat Oral 1000 mg/kg/day NOAEL Maternal Toxicity

Embryo / Fetal Development
- Rat Oral 2000 mg/kg/day NOAEL Fetotoxicity

Lincomycin Hydrochloride
SAFETY DATA SHEET

Material Name: Lincomycin Hydrochloride/Spectinomycin Sulfate Tetrahydrate (50) Water Soluble Powder
Revision date: 22-Feb-2014

11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th></th>
<th>Type</th>
<th>Organism</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial Mutagenicity</td>
<td>(Ames)</td>
<td>Salmonella</td>
<td>Negative</td>
</tr>
<tr>
<td>Salicylic Acid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In Vitro Chromosome Aberration</td>
<td>Chinese Hamster Ovary (CHO) cells</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>In Vitro Unscheduled DNA Synthesis</td>
<td>Rat Hepatocyte</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>In Vivo Micronucleus</td>
<td>Mouse Bone Marrow</td>
<td>Negative</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Type</th>
<th>Organism</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammalian Cell Mutagenicity</td>
<td></td>
<td>Mouse Lymphoma</td>
<td>Negative</td>
</tr>
<tr>
<td>In Vivo Micronucleus</td>
<td>Rat</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>Direct DNA Interaction</td>
<td>Human Lymphocytes</td>
<td>Negative</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Type</th>
<th>Organism</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial Mutagenicity</td>
<td>(Ames)</td>
<td>Salmonella</td>
<td>Negative</td>
</tr>
<tr>
<td>Sucrose</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Type</th>
<th>Organism</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carcinogen Status:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation 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)

**Spectinomycin Sulfate Tetrahydrate**
- *Selenastrum capricornutum* (Green Alga): OECD EC50, 72 Hours, 1.18 mg/L
- *Daphnia magna* (Water Flea): TAD EC50, 48 Hours, >1000 mg/L
- *Oncorhynchus mykiss* (Rainbow Trout): OECD LC50, 96 Hours, >118 mg/L

**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

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

Persistence and Degradability: No data available

Bio-accumulative Potential:
- **Spectinomycin Sulfate Tetrahydrate**: No data available
- **Lincomycin Hydrochloride**: Measured 7.4, Log D -2.44

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

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision B

Spectinomycin Sulfate Tetrahydrate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

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

Sucrose
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register: Present
- EU EINECS/ELINCS List: 200-334-9

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction

Xi - Irritant

R43 - May cause sensitization by skin contact.

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.
SAFETY DATA SHEET

Material Name: Lincomycin Hydrochloride/Spectinomycin Sulfate Tetrahydrate (50) Water Soluble Powder
Revision date: 22-Feb-2014
Version: 4.0

Prepared by: Toxicology and Hazard Communication Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this 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