

# SAFETY DATA SHEET



Revision date: 22-Feb-2014

Version: 4.0

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

### Product Identifier

**Material Name:** Lincomycin Hydrochloride/Spectinomycin Sulfate Tetrahydrate (50) Water Soluble Powder

**Trade Name:** L-S 50 Water Soluble Powder  
**Synonyms:** Linco-Spectin; Linco-Spectin 50  
**Chemical Family:** Mixture

### 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

### Details of the Supplier of the Safety Data Sheet

Zoetis Inc.  
100 Campus Drive, P.O. Box 651  
Florham Park, New Jersey 07932 (USA)  
Rocky Mountain Poison Control Center Phone: 1-866-531-8896  
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.  
Mercuriusstraat 20  
1930 Zaventem  
Belgium

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

**Emergency telephone number:**  
**International CHEMTREC (24 hours):** +1-703-527-3887

## 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

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### 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. Hazardous Substance. Non-Dangerous Goods.

### Australian Hazard Classification (NOHSC):

#### 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

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Spectinomycin Sulfate Tetrahydrate	64058-48-6	Not Listed	Xi;R43	Skin Sens. 1 (H317)	44
Lincomycin Hydrochloride	859-18-7	212-726-7	Xi;R43	Skin Sens. 1 (H317)	22
Sucrose	57-50-1	200-334-9	Not Listed	Not Listed	*

### 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

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### 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

- Notes to Physician:** None

### 5. FIRE-FIGHTING MEASURES

- Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, 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:** 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

- Measures for Cleaning / Collecting:** 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.

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### 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/m<sup>3</sup>

#### Lincomycin Hydrochloride

Zoetis OEL TWA 8-hr 100µg/m<sup>3</sup>

#### Sucrose

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	10 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	6 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

#### 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.

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### 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

<b>Physical State:</b>	Powder	<b>Color:</b>	White
<b>Odor:</b>	Slight	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	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)**  
No data available

**Spectinomycin Sulfate Tetrahydrate**

Measured 7.4 Log D -2.44

**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:**

<b>Autoignition Temperature (Solid) (°C):</b>	No data available
<b>Flammability (Solids):</b>	No data available
<b>Flash Point (Liquid) (°C):</b>	No data available
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available

### 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**

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### 11. TOXICOLOGICAL INFORMATION

**General Information:** Toxicological 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 LD50 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**

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### 11. TOXICOLOGICAL INFORMATION

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)

##### **Spectinomycin Sulfate Tetrahydrate**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vitro</i> Unscheduled DNA Synthesis	Rat Hepatocyte	Negative
<i>In Vivo</i> Micronucleus	Mouse Bone Marrow	Negative

##### **Lincomycin Hydrochloride**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Mammalian Cell Mutagenicity	Mouse Lymphoma	Negative
<i>In Vivo</i> Micronucleus	Rat	Negative
Direct DNA Interaction	Human Lymphocytes	Negative

##### **Sucrose**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
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#### Carcinogen Status:

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

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## 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**

<i>Selenastrum capricornutum</i> (Green Alga)	OECD	EC50	72 Hours	1.18 mg/L
<i>Daphnia magna</i> (Water Flea)	TAD	EC50	48 Hours	>1000 mg/L
<i>Oncorhynchus mykiss</i> (Rainbow Trout)	OECD	LC50	96 Hours	>118 mg/L

##### **Lincomycin Hydrochloride**

<i>Lepomis macrochirus</i> (Bluegill Sunfish)	ASTM	LC50	96 Hours	>980 mg/L
<i>Daphnia magna</i> (Water Flea)	ASTM	EC50	48 Hours	>900 mg/L
<i>Anabaena flos-aquae</i> (Cyanobacteria)	OECD	EC50	72 Hours	0.03 mg/L
<i>Salmo gairdneri</i> (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:** No data available

##### **Spectinomycin Sulfate Tetrahydrate**

Measured 7.4 Log D -2.44

##### **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.



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### 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.

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**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**