



MATERIAL SAFETY DATA SHEET

Revision date: 06-Aug-2009

Version: 2.5

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

Pfizer Animal Health
Pfizer Inc
235 East 42nd Street
New York, NY 10017
Poison Control Center Phone: 1-866-531-8896
Technical Services Phone: 1-800-366-5288
Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

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

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Lincomycin Hydrochloride/Spectinomycin Sulfate Tetrahydrate 100

Trade Name: Linco-Spectin® 100; Linco-Spectin® 100 Soluble Powder
Chemical Family: Mixture
Intended Use: Veterinary product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: White powder
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.

Additional Hazard Information:
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.

EU Indication of danger: Irritant

EU Hazard Symbols:
Xi



EU Risk Phrases:

R43 - May cause sensitization by skin contact.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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.

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2. HAZARDS IDENTIFICATION

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Lincomycin Hydrochloride	859-18-7	212-726-7	Xi;R43	33.3 g
Spectinomycin Sulfate Tetrahydrate	64058-48-6	Not listed	Xi;R43	66.7g

Additional Information: 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.

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire. May include oxides of carbon and products of sulfur, nitrogen and chlorine.

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

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

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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: Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Spectinomycin Sulfate Tetrahydrate
Pfizer OEL TWA-8 Hr: 2000 µg/m³

The exposure limit(s) listed for solid components are only relevant if dust may be generated. Refer to available public information for specific member state Occupational Exposure Limits.

Analytical Method: Analytical method available for Spectinomycin. Contact Pfizer Inc for further information.

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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

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.

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:	Powder	Color:	White
Odor:	Slight	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

Solubility: Soluble: Water

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9. PHYSICAL AND CHEMICAL PROPERTIES

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
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

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)

Lincomycin Hydrochloride

Rat Oral LD 50 > 4000 mg/kg
Rat Intravenous LD 50 342 mg/kg
Mouse Intravenous LD 50 214 mg/kg
Rat Subcutaneous LD 50 9778 mg/kg

Spectinomycin Sulfate Tetrahydrate

Rat Oral LD 50 >5000 mg/kg
Mouse Intraperitoneal LD 50 3577 mg/kg
Mouse Intravenous LD 50 1022 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.

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)

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

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

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

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11. TOXICOLOGICAL INFORMATION

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

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

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

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

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

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 of the formulation 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

<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

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

Aquatic Toxicity Comments:

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

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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. 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

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: Xi
EU Indication of danger: Irritant

EU Risk Phrases:
R43 - May cause sensitization by skin contact.

EU Safety Phrases:
S22 - Do not breathe dust.
S24 - Avoid contact with skin.
S37 - Wear suitable gloves.

OSHA Label:
WARNING
May cause allergic skin reaction.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision B



Lincomycin Hydrochloride
Australia (AICS):
EU EINECS/ELINCS List

Listed
212-726-7

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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 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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