

SAFETY DATA SHEETS

This SDS packet was issued with item:

078912797

N/A



MATERIAL SAFETY DATA SHEET

Revision date: 06-Sep-2012

Version: 2.3

Page 1 of 7

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
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

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
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):

MATERIAL SAFETY DATA SHEET

Material Name: Lincomycin Hydrochloride/Spectinomycin
Sulfate Tetrahydrate (50) Water Soluble Powder
Revision date: 06-Sep-2012

Page 2 of 7

Version: 2.3

2. HAZARDS IDENTIFICATION

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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Spectinomycin Sulfate Tetrahydrate	64058-48-6	Not Listed	Xi;R43	44
Lincomycin Hydrochloride	859-18-7	212-726-7	Xi;R43	22
Sucrose	57-50-1	200-334-9	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 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: Not determined

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

Fire / Explosion Hazards: No data available

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

MATERIAL SAFETY DATA SHEET

Material Name: Lincomycin Hydrochloride/Spectinomycin
Sulfate Tetrahydrate (50) Water Soluble Powder
Revision date: 06-Sep-2012

Page 3 of 7

Version: 2.3

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.

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 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

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

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

Sucrose

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

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).

MATERIAL SAFETY DATA SHEET

Material Name: Lincomycin Hydrochloride/Spectinomycin
Sulfate Tetrahydrate (50) Water Soluble Powder
Revision date: 06-Sep-2012

Page 4 of 7

Version: 2.3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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		

10. STABILITY AND REACTIVITY

Chemical 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)

Spectinomycin Sulfate Tetrahydrate

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

Lincomycin Hydrochloride

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

MATERIAL SAFETY DATA SHEET

Material Name: Lincomycin Hydrochloride/Spectinomycin Sulfate Tetrahydrate (50) Water Soluble Powder
Revision date: 06-Sep-2012

Page 5 of 7

Version: 2.3

11. TOXICOLOGICAL INFORMATION

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

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)	Salmonella	Negative
In Vitro Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
In Vitro Unscheduled DNA Synthesis	Rat Hepatocyte	Negative
In Vivo Micronucleus	Mouse Bone Marrow	Negative

Lincomycin Hydrochloride

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

Sucrose

Bacterial Mutagenicity (Ames)	Salmonella	Negative
-------------------------------	------------	----------

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

MATERIAL SAFETY DATA SHEET

Material Name: Lincomycin Hydrochloride/Spectinomycin
Sulfate Tetrahydrate (50) Water Soluble Powder
Revision date: 06-Sep-2012

Page 6 of 7

Version: 2.3

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)

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.

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

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.

MATERIAL SAFETY DATA SHEET

Material Name: Lincomycin Hydrochloride/Spectinomycin
Sulfate Tetrahydrate (50) Water Soluble Powder
Revision date: 06-Sep-2012

Page 7 of 7

Version: 2.3

15. REGULATORY INFORMATION

OSHA Label:

WARNING

May cause allergic skin reaction.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision B



Lincomycin Hydrochloride

Australia (AICS):

Present

EU EINECS/ELINCS List

212-726-7

Sucrose

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 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 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 2 - Hazard Identification. 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:

Product Stewardship 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

SAFETY DATA SHEET



Revision date: 24-Mar-2015

Version: 3.2

Page 1 of 10

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

Product Identifier

Material Name: Lincomycin Hydrochloride/Spectinomycin Sulfate Tetrahydrate Sterile Solution

Trade Name: Linco-Spectin®

Synonyms: Linco-Spectin® injectable, Linco-Spectin® sterile solution, Linco-Spectin® VET

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 and Drug 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: Liquid

Classification of the Substance or Mixture

GHS - Classification

Skin Sensitization: Category 1

EU Classification:

EU Indication of danger: Xi - 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

SAFETY DATA SHEET

Material Name: Lincomycin Hydrochloride/Spectinomycin
Sulfate Tetrahydrate Sterile Solution
Revision date: 24-Mar-2015

Page 2 of 10

Version: 3.2

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
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 . Signs and symptoms might include redness, swelling, blurred vision or pain. May cause skin irritation. (based on components) 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.

Known Clinical Effects:

The most common adverse effects seen during clinical use of this drug include nausea , vomiting , fever , 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.

Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

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)	10
Lincomycin Hydrochloride	859-18-7	212-726-7	Xi;R43	Skin Sens.1 (H317)	5
Benzyl Alcohol	100-51-6	202-859-9	Xn; R20/22	Acute Tox.4 (H302) Acute Tox.4 (H332)	1

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Water	7732-18-5	231-791-2	Not Listed	Not Listed	*

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.

SAFETY DATA SHEET

Material Name: Lincomycin Hydrochloride/Spectinomycin
Sulfate Tetrahydrate Sterile Solution
Revision date: 24-Mar-2015

Page 3 of 10

Version: 3.2

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

- 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.

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

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 Products:** Formation of toxic gases is possible during heating or fire.
- Fire / Explosion Hazards:** Not flammable.

Advice for Fire-Fighters

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

- Additional Information:** This product is a nonflammable aqueous solution.

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 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.

SAFETY DATA SHEET

Material Name: Lincomycin Hydrochloride/Spectinomycin
Sulfate Tetrahydrate Sterile Solution
Revision date: 24-Mar-2015

Page 4 of 10

Version: 3.2

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. 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
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

Benzyl Alcohol

Bulgaria OEL - TWA 5.0 mg/m³

Czech Republic OEL - TWA 40 mg/m³

Finland OEL - TWA 10 ppm

45 mg/m³

Latvia OEL - TWA 5 mg/m³

Lithuania OEL - TWA 5 mg/m³

Poland OEL - TWA 240 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.

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.

SAFETY DATA SHEET

Material Name: Lincomycin Hydrochloride/Spectinomycin
Sulfate Tetrahydrate Sterile Solution
Revision date: 24-Mar-2015

Page 5 of 10

Version: 3.2

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	No data available.
Odor:	Slight	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility: No data available
Water Solubility: No data available
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

Lincomycin Hydrochloride

Measured 6-8 Log D 2.55

Spectinomycin Sulfate Tetrahydrate

Measured 7.4 Log D -2.44

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

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
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 Products:	Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

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)

SAFETY DATA SHEET

Material Name: Lincomycin Hydrochloride/Spectinomycin Sulfate Tetrahydrate Sterile Solution
Revision date: 24-Mar-2015

Page 6 of 10

Version: 3.2

11. TOXICOLOGICAL INFORMATION

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

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

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.

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

Spectinomycin Sulfate Tetrahydrate

Skin Irritation	Rabbit	No effect
Eye Irritation	Rabbit	Minimal

Benzyl Alcohol

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

Irritation / Sensitization Comments: May cause eye irritation.

Skin Irritation / Sensitization May cause skin irritation. May cause sensitisation by skin contact.

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))

SAFETY DATA SHEET

Material Name: Lincomycin Hydrochloride/Spectinomycin
Sulfate Tetrahydrate Sterile Solution
Revision date: 24-Mar-2015

Page 7 of 10

Version: 3.2

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.

SAFETY DATA SHEET

Material Name: Lincomycin Hydrochloride/Spectinomycin Sulfate Tetrahydrate Sterile Solution
Revision date: 24-Mar-2015

Page 8 of 10

Version: 3.2

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

<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

Benzyl Alcohol

<i>Pimephales promelas</i> (Fathead Minnow)	EPA	LC50	96 Hours	460 mg/L
<i>Daphnia magna</i> (Water Flea)	OECD	EC50	48 Hours	230 mg/L
<i>Pseudokirchneriella subcapitata</i> (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

<i>Daphnia magna</i> (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
----------	-----	-------	------

Spectinomycin Sulfate Tetrahydrate

Measured	7.4	Log D	-2.44
----------	-----	-------	-------

Mobility in Soil:

No data available

SAFETY DATA SHEET

Material Name: Lincomycin Hydrochloride/Spectinomycin
Sulfate Tetrahydrate Sterile Solution
Revision date: 24-Mar-2015

Page 9 of 10

Version: 3.2

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

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.



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

Benzyl Alcohol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed

SAFETY DATA SHEET

Material Name: Lincomycin Hydrochloride/Spectinomycin
Sulfate Tetrahydrate Sterile Solution
Revision date: 24-Mar-2015

Page 10 of 10

Version: 3.2

15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-859-9

Water

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	231-791-2

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
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Xi - Irritant
Xn - Harmful

R43 - May cause sensitization by skin contact.
R20/22 - Harmful by inhalation and if swallowed.

Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 5 - Fire Fighting Measures. Updated Section 11 - Toxicology Information.

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