

SAFETY DATA SHEET



1. Identification

Product identifier	Lincomycin Hydrochloride/Spectinomycin Sulfate Tetrahydrate Sterile Solution
Other means of identification	
Synonyms	Linco-Spectin® * Linco-Spectin * Linco-Spectin® injectable * Linco-Spectin® sterile solution * LINCO-SPECTIN® Antibiotic Injectable Solution * Linco-Spectin® VET
Recommended use	Veterinary product used as antibiotic agent
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (US)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-888-963-8471
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (EU)	Zoetis Belgium S.A. Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium
Telephone:	+32 10 808080
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Sensitization, skin	Category 1
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	

Label elements



Signal word	Warning
Hazard statement	May cause an allergic skin reaction.
Precautionary statement	
Prevention	Avoid breathing mist or vapor. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves.
Response	If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.

Supplemental information

May cause eye irritation. May cause skin irritation. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. The most common adverse effects reported with clinical use were diarrhea, nausea, rash, and vomiting. Effects on blood and blood-forming organs have also occurred.

3. Composition/information on ingredients**Mixtures**

Chemical name	Common name and synonyms	CAS number	%
Spectinomycin Sulfate Tetrahydrate		64058-48-6	10
Lincomycin Hydrochloride		859-18-7	5
Benzyl alcohol		100-51-6	0.9
Water for Injection		7732-18-5	*

Composition comments

* Non-hazardous Ingredients

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. First-aid measures**Inhalation**

Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.

Skin contact

In the case of skin contact, immediately wash the skin with plenty of soap and water. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Wash clothing separately before reuse.

Eye contact

Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion

Rinse mouth. Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

Most important symptoms/effects, acute and delayed

Direct contact with eyes may cause temporary irritation. Mild skin irritation. May cause an allergic skin reaction. Dermatitis. Rash. The most common adverse effects reported with clinical use were diarrhea, nausea, rash, and vomiting.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

General information

For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

5. Fire-fighting measures**Suitable extinguishing media**

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).

Unsuitable extinguishing media

Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical

During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions

Move containers from fire area if you can do so without risk.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards

No unusual fire or explosion hazards noted.

6. Accidental release measures**Personal precautions, protective equipment and emergency procedures**

Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Ventilate closed spaces before entering them. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up

Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Avoid release to the environment.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Clean surface thoroughly to remove residual contamination.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground.

Environmental precautions**7. Handling and storage****Precautions for safe handling**

Wear personal protective equipment. Provide adequate ventilation. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Avoid prolonged exposure. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash thoroughly after handling. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Store in a well-ventilated place. @ 15-30°C (59-86°F).. Keep away from heat, sparks and open flame. Do not store in direct sunlight. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection**Occupational exposure limits**

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Zoetis**Components**

Components	Type	Value
Lincomycin Hydrochloride (CAS 859-18-7)	TWA	100 µg/m ³
Spectinomycin Sulfate Tetrahydrate (CAS 64058-48-6)	TWA	2000 µg/m ³

US. Workplace Environmental Exposure Level (WEEL) Guides**Components**

Components	Type	Value
Benzyl alcohol (CAS 100-51-6)	TWA	44.2 mg/m ³ 10 ppm

Biological limit values

No biological exposure limits noted for the ingredient(s).

Control banding approach

Not available.

Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment**Eye/face protection**

If contact is likely, safety glasses with side shields are recommended.

Skin protection**Hand protection**

Wear protective gloves. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Other

Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection

No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. 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.

Thermal hazards

Not applicable.

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties**Appearance**

Physical state	Liquid.
Form	Liquid.
Color	Not available.
Odor	Slight.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur. May include hydrogen chloride.

11. Toxicological information**Information on likely routes of exposure**

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact May cause an allergic skin reaction.

Benzyl alcohol

Species: Guinea Pig
Severity: Moderate

Skin contact

Benzyl alcohol

Species: Rabbit
Severity: Minimal

Spectinomycin Sulfate Tetrahydrate

Species: Rabbit
Severity: No effect**Eye contact**

Direct contact with eyes may cause temporary irritation.

Spectinomycin Sulfate Tetrahydrate

Species: Rabbit
Severity: Minimal

Benzyl alcohol

Species: Rabbit
Severity: Severe**Ingestion**

Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea.

Symptoms related to the physical, chemical and toxicological characteristics

Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. Mild skin irritation. May cause an allergic skin reaction. Dermatitis. Rash. The most common adverse effects reported with clinical use were diarrhea, nausea, rash, and vomiting.

Information on toxicological effects**Acute toxicity**

Not acutely toxic

Components**Species****Test Results**

Benzyl alcohol (CAS 100-51-6)

Acute**Dermal**

LD50

Rabbit

2000 mg/kg

Inhalation

LC50

Rat

> 4.178 mg/L
1000 mg/l, 8 Hours**Oral**

LD50

Mouse

1580 mg/kg

Rat

1230 mg/kg

Lincomycin Hydrochloride (CAS 859-18-7)

Acute**Intravenous**

LD50

Mouse

214 mg/kg

Oral

LD50

Rat

> 4000 mg/kg

Other

LD50

Rat

342 mg/kg (Para-periosteal)

Subcutaneous

LD50

Rat

9778 mg/kg

Chronic**Oral**

NOAEL

Dog

100 mg/kg/day, 6 months (Immune system)

Subacute**Oral**

NOAEL

Rat

300 mg/kg/day, 30 days (No effects at maximum dose)

Subcutaneous

NOAEL

Rat

60 mg/kg/day, 30 days (None identified)

Subchronic**Oral**

LOAEL

Dog

400 mg/kg/day, 3 months (None identified)

Components	Species	Test Results
NOAEL	Rat	300 mg/kg/day, 3 months (None identified)
Spectinomycin Sulfate Tetrahydrate (CAS 64058-48-6)		
Acute		
Intravenous		
LD50	Mouse	1022 mg/kg
Oral		
LD50	Rat	> 5000 mg/kg
Other		
LD50	Mouse	3577 mg/kg [Sub-tenon injection (eye)]
Subchronic		
Oral		
LOAEL	Rat	3000 mg/kg/day, 13 weeks (Target organ(s): None identified)
NOAEL	Dog	50 mg/kg/day, 90 days (Target organ(s): None identified)
	Rat	400 mg/kg/day, 13 weeks (Target organ(s): None identified)
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Corrosivity		
Spectinomycin Sulfate Tetrahydrate	Severity: No effect	
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Eye Contact		
Spectinomycin Sulfate Tetrahydrate	Species: Rabbit Severity: Minimal	
Benzyl alcohol	Species: Rabbit Severity: Severe	
Respiratory or skin sensitization	In the event of accidental injection, an allergic reaction may occur.	
Respiratory sensitization	Not a respiratory sensitizer.	
Skin sensitization	May cause an allergic skin reaction.	
Skin sensitization		
Spectinomycin Sulfate Tetrahydrate	Severity: Sensitizer	
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Mutagenicity		
Lincomycin Hydrochloride	Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella	
Spectinomycin Sulfate Tetrahydrate	Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella	
Lincomycin Hydrochloride	Direct DNA Interaction Result: Negative Species: Human Lymphocytes	
Spectinomycin Sulfate Tetrahydrate	In Vitro Chromosome Aberration Result: Negative Species: Chinese Hamster Ovary (CHO) cells	

Mutagenicity

Spectinomycin Sulfate Tetrahydrate

In Vitro Unscheduled DNA Synthesis

Result: Negative

Species: Rat Hepatocyte

In Vivo Micronucleus

Result: Negative

Species: Mouse Bone Marrow

Lincomycin Hydrochloride

In Vivo Micronucleus

Result: Negative

Species: Rat

Mammalian Cell Mutagenicity

Result: Negative

Species: Mouse Lymphoma

Carcinogenicity

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

This product is not expected to cause reproductive or developmental effects. This compound can cross the placenta in pregnant women. may be secreted in human breast milk.

Developmental effects

Lincomycin Hydrochloride

100 mg/kg Prenatal & Postnatal Development, Not

Teratogenic

Result: NOEL

Species: Rat

Organ: Oral

Spectinomycin Sulfate Tetrahydrate

1000 mg/kg/day Embryo / Fetal Development, (Maternal Toxicity)

Result: NOAEL

Species: Rat

Organ: Oral

2000 mg/kg/day Embryo / Fetal Development, (Fetotoxicity)

Result: NOAEL

Species: Rat

Organ: Oral

Lincomycin Hydrochloride

30 mg/kg/day Peri-/Postnatal Development, No effects at maximum dose

Result: NOAEL

Species: Rat

Organ: Subcutaneous

300 mg/kg/day Embryo / Fetal Development, Not Teratogenic

Result: NOAEL

Species: Rat

Organ: Subcutaneous

75 mg/kg/day Fertility and Embryonic Development, No effects at maximum dose

Result: NOAEL

Species: Rat

Organ: Subcutaneous

Reproductivity

Lincomycin Hydrochloride

100 mg/kg 2 Generation Reproductive Toxicity, Fetotoxicity
 Result: LOAEL
 Species: Rat
 Organ: Oral

Spectinomycin Sulfate Tetrahydrate

2000 mg/kg/day Reproductive & Fertility, (Maternal Toxicity, Paternal toxicity, Fetotoxicity)
 Result: NOAEL
 Species: Rat
 Organ: Oral

400 mg/kg/day Reproductive & Fertility, (Maternal toxicity, Paternal toxicity, Fetotoxicity)
 Result: NOEL
 Species: Rat
 Organ: Oral

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Due to partial or complete lack of data the classification is not possible. This product may affect blood and blood forming organs through prolonged or repeated exposure.

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Components		Species	Test Results
Benzyl alcohol (CAS 100-51-6)			
Aquatic			
Algae	EC50	Pseudokirchneriella subcapitata (Green Alga)	500 mg/L, 72 Hours
Crustacea	EC50	Daphnia magna (Water Flea)	230 mg/L, 48 Hours 66 mg/L, 21 Day(s) Reproduction
Fish	LC50	Pimephales promelas (Fathead Minnow)	460 mg/L, 96 Hours
<i>Acute</i>			
Fish	LC50	Bluegill (Lepomis macrochirus)	10 mg/l, 96 hours
Lincomycin Hydrochloride (CAS 859-18-7)			
	EC50	Anabaena flos-aquae (Cyanobacteria)	0.03 mg/L, 72 Hours
	LC50	Salmo gairdneri (Trout)	> 980 mg/L, 96 Hours
Aquatic			
Crustacea	EC50	Daphnia magna (Water Flea)	> 900 mg/L, 48 Hours
Fish	LC50	Lepomis macrochirus (Bluegill Sunfish)	> 980 mg/L, 96 Hours
Spectinomycin Sulfate Tetrahydrate (CAS 64058-48-6)			
Aquatic			
Algae	EC50	Selenastrum capricornutum (Green Alga)	1.18 mg/L, 72 Hours
Crustacea	EC50	Daphnia magna (Water Flea)	> 1000 mg/L, 48 Hours
Fish	LC50	Oncorhynchus mykiss (Rainbow Trout)	> 118 mg/L, 96 Hours

Persistence and degradability No data is available on the degradability of this product.

Biodegradability

Percent degradation (Aerobic biodegradation)

Benzyl alcohol 92 - 96 %
Test Duration: 28 days

Bioaccumulative potential Not expected to bioaccumulate.

Partition coefficient n-octanol / water (log Kow)

Benzyl alcohol 1.1
Lincomycin Hydrochloride 2.55, pH 6-8
Spectinomycin Sulfate Tetrahydrate -2.44, (Log D, measured, pH 7.4)

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Avoid release to the environment. 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. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code None known.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner.

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes
Classified hazard categories Respiratory or skin sensitization
SARA 313 (TRI reporting)
 Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
 Not regulated.
Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
 Not regulated.
Safe Drinking Water Act (SDWA) Not regulated.

US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
 A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 02-11-2015
Revision date 03-22-2022
Version # 04

Disclaimer 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. The information in the sheet was written based on the best knowledge and experience currently available.

Revision information Identification: Recommended restrictions
 Composition / Information on Ingredients: Ingredients
 Composition/information on ingredients: Component information
 First-aid measures: Ingestion
 First-aid measures: Skin contact
 Accidental release measures: Methods and materials for containment and cleaning up
 Handling and storage: Conditions for safe storage, including any incompatibilities
 Toxicological information: Acute toxicity
 Toxicological information: Respiratory or skin sensitization
 Toxicological information: Ingestion
 Disposal considerations: Disposal instructions
 GHS: Classification