

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 (USA)	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 (CA)	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	productsupport@zoetis.com
Product Support	1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at <https://www.zoetis.ca/sds/sds.aspx>

Supplier Not available.

2. Hazard identification

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

Label elements



Signal word	Warning
Hazard statement	May cause an allergic skin reaction.
Precautionary statement	
Prevention	Avoid breathing mist or vapour. Contaminated work clothing should 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. Take off contaminated clothing and wash it before reuse.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.

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.

Other hazards None known.

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	*

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments * Non-hazardous Ingredients

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 centre 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 vapour. 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 vapour. 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****Zoetis****Components****Type****Value**

Lincomycin Hydrochloride (CAS 859-18-7)

TWA

100 µg/m³

Spectinomycin Sulfate Tetrahydrate (CAS 64058-48-6)

TWA

2000 µg/m³

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.

Colour

Not available.

Odour	Slight.
Odour 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.
Vapour pressure	Not available.
Vapour 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.
Oxidising properties	Not oxidising.

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 oxidising 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

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

Eye contact
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)
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

Components	Species	Test Results
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 sensitisation	In the event of accidental injection, an allergic reaction may occur.	
Respiratory sensitisation	Not a respiratory sensitiser.	
Skin sensitisation	May cause an allergic skin reaction.	
Skin Sensitisation		
Spectinomycin Sulfate Tetrahydrate		Severity: Sensitiser
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
		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

Mutagenicity
Lincomycin Hydrochloride

Mammalian Cell Mutagenicity
Result: Negative
Species: Mouse Lymphoma

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

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) Toxicity for reproduction
Fish	LC50	Pimephales promelas (Fathead Minnow)	460 mg/l, 96 Hours
Acute			
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

TDG	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

Canadian regulations	This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.
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Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Precursor Control Regulations

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto Protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

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

Country(s) or region	Inventory name	On inventory (yes/no)*
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

Issue date 18-April-2017

Revision date 22-March-2022

Version No. 02

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 sensitisation
Toxicological information: Ingestion
Disposal considerations: Disposal instructions
GHS: Classification