

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 of the chemical and restrictions on use	
Recommended use	Veterinary product used as antibiotic agent
Restrictions on use	Not for human use
Details of manufacturer or importer	
Company Name (AU)	Zoetis Australia Pty Ltd ABN 94 156 476 425 Level 6, 5 Rider Boulevard Rhodes NSW 2138 AUSTRALIA
Tel	1800 814 883
Fax	(02) 8876 0444
Email	australia.animalhealth@zoetis.com
Emergency Phone	1800 814 883 (all hours)
Police and Fire Brigade	Dial 000
If ineffective	Dial Poisons Information Centre (13 1126 from anywhere in Australia)

2. Hazard(s) identification

Classification of the hazardous chemical

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

Label elements, including precautionary statements

Hazard symbol(s)



Exclamation mark

Signal word	Warning
Hazard statement(s)	May cause an allergic skin reaction.
Precautionary statement(s)	

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 soap and 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.

Other hazards which do not result in classification 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

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Spectinomycin Sulfate Tetrahydrate	64058-48-6	10
Lincomycin Hydrochloride	859-18-7	5
Benzyl alcohol	100-51-6	1
Water	7732-18-5	*

Composition comments * Non-hazardous Ingredients

4. First-aid measures

Description of necessary 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	Remove contaminated clothing immediately and wash skin with soap and water. Get medical attention if irritation develops and persists. 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 POISON CENTRE or doctor/physician if you feel unwell. If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.

Personal protection for first-aid responders 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.

Symptoms caused by exposure 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.

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

5. Fire-fighting measures

Extinguishing media

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 fire fighters 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.

Hazchem Code None.

General fire hazards No unusual fire or explosion hazards noted.

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

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained.

For emergency responders Keep unnecessary personnel away. Ensure adequate ventilation. Use personal protection recommended in Section 8 of the SDS. Ventilate the contaminated area. Do not breathe mist or vapour. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

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. Following product recovery, flush area with water.

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.

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 and personal protection

Control parameters Follow standard monitoring procedures.

Occupational exposure limits

Zoetis 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

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

Exposure guidelines No exposure standards allocated.

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, for example personal protective equipment (PPE)

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.

Hygiene measures 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	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
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 physical and chemical parameters	
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 possible 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

Benzyl alcohol Species: Rabbit
Severity: Severe

Ingestion Expected to be a low ingestion hazard.

Symptoms related to exposure 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.

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

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

Components	Species	Test results
Oral		
LD50	Rat	> 5000 mg/kg
Other		
LD50	Mouse	3577 mg/kg [Sub-tenon injection (eye)]
<u>Subchronic</u>		
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/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		
Respiratory sensitisation	Not a respiratory sensitizer.	
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

Mutagenicity

Lincomycin Hydrochloride

In Vivo Micronucleus

Result: negative

Species: Rat

Mammalian Cell Mutagenicity

Result: negative

Species: Mouse Lymphoma

Carcinogenicity

Due to partial or complete lack of data the classification is not possible.

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)	EC50	Daphnia magna (Water Flea) 230 mg/l, 48 Hours
		66 mg/l, 21 day(s) Toxicity for reproduction
		Pseudokirchneriella subcapitata (Green Alga) 500 mg/l, 72 Hours
	LC50	Pimephales promelas (Fathead Minnow) 460 mg/l, 96 Hours
Aquatic		
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
		Daphnia magna (Water Flea) > 900 mg/l, 48 Hours
	LC50	Lepomis macrochirus (Bluegill Sunfish) > 980 mg/l, 96 Hours
		Salmo gairdneri (Trout) > 980 mg/l, 96 Hours
Spectinomycin Sulfate Tetrahydrate (CAS 64058-48-6)	EC50	Daphnia magna (Water Flea) > 1000 mg/l, 48 Hours
		Selenastrum capricornutum (Green Alga) 1.18 mg/l, 72 Hours
	LC50	Oncorhynchus mykiss (Rainbow Trout) > 118 mg/l, 96 Hours
Persistence and degradability	No data is available on the degradability of this product.	
Bioaccumulative potential	Not expected to bioaccumulate.	
Partition coefficient n-octanol / water (log Kow)		
Lincomycin Hydrochloride	2.55, pH 6-8	
Spectinomycin Sulfate Tetrahydrate	-2.44, (Log D, measured, pH 7.4)	

Mobility in soil No data available for this product.

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 methods Avoid release to the environment. Do not allow this material to drain into sewers/water supplies. Do not discharge into drains, water courses or onto the ground. 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.

Residual waste 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 (see: Disposal instructions).

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

14. Transport information

ADG

Not regulated as dangerous goods.

RID

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

Safety, health and environmental regulations

National regulations

This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals (23/12/2011).

APVMA Registration Number: 38692

Poison Schedule (Product) - Schedule 4

This SDS replaces version: Issued October 2016

High Volume Industrial Chemicals (HVIC)

Benzyl alcohol (CAS 100-51-6)	10000 - 99999 TONNES See the regulation for additional information.
Water (CAS 7732-18-5)	1000 - 9999 TONNES See the regulation for additional information.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

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 Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No

Country(s) or region	Inventory name	On inventory (yes/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
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
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	Product and Company Identification: Synonyms Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Multiple Properties