Issue date: 18-April-2017 Revision date: 22-March-2022 Supersedes date: 18-April-2017 Version number: 02

SAFETY DATA SHEET



1. Identification

Product identifier Lincomycin Hydrochloride/Spectinomycin Sulfate Tetrahydrate Sterile Solution

Other means of identification

Synonyms 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 productsupport.au@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.

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 which do not

result in classification

None known.

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	0.9
Water for Injection	7732-18-5	*

Composition comments

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 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.

Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if Eye contact

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 unconsious person.

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

Hazchem code

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

equipment/instructions

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

For emergency responders

Personal precautions, protective equipment and emergency procedures

For non-emergency

Keep unnecessary personnel away.

personnel

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.

^{*} Non-hazardous Ingredients

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.

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

Components	Туре	Value	
Lincomycin Hydrochloride (CAS 859-18-7)	TWA	100 μg/m3	
Spectinomycin Sulfate Tetrahydrate (CAS 64058-48-6)	TWA	2000 μg/m³	

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

Components	Туре	Value	Form
Benzyl alcohol (CAS 100-51-6)	TWA	22 mg/m3	Vapour and aerosol.
·		5 ppm	Vapour and aerosol.

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.

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. рΗ Not available. Not available. Melting point/freezing point Initial boiling point and boiling Not available.

range

Not available. Flash point **Evaporation rate** Not available. Flammability (solid, gas) Not applicable. Upper/lower flammability or explosive limits

Explosive limit - lower (%) Not available. Not available. Explosive limit - upper

(%)

Not available. Vapour pressure Not available. Vapour density Relative density Not available.

Solubility(ies)

Not available. Solubility (water) Not available. **Partition coefficient**

(n-octanol/water)

Not available. **Auto-ignition temperature** Not available. **Decomposition temperature** Not available. **Viscosity**

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.

Contact with incompatible materials. Conditions to avoid

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

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

inhalation hazard.

May cause an allergic skin reaction. Skin contact

Benzyl alcohol Species: Guinea Pig

Severity: Moderate

Species: Rabbit Severity: Minimal Skin contact

Spectinomycin Sulfate Tetrahydrate Species: Rabbit

Severity: No effect

Direct contact with eyes may cause temporary irritation. **Eve contact**

Spectinomycin Sulfate Tetrahydrate Species: Rabbit

Severity: Minimal

Benzyl alcohol Species: Rabbit

Severity: Severe

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

Direct contact with eyes may cause temporary irritation. Exposed individuals may Symptoms related to exposure

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

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

NOAEL 300 mg/kg/day, 3 months (None identified) Rat

Components Species Test Results

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/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 Mutagenicity

Spectinomycin Sulfate Tetrahydrate 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.

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

Material name: Lincomycin Hydrochloride/Spectinomycin Sulfate Tetrahydrate Sterile Solution

Reproductivity

Spectinomycin Sulfate Tetrahydrate 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

The product is not classified as environmentally hazardous. However, this does not exclude the **Ecotoxicity**

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 Tetrahydr	ate (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 av	vailable on the degradability of this product	

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

Material name: Lincomycin Hydrochloride/Spectinomycin Sulfate Tetrahydrate Sterile Solution 1312

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. 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.

Dispose of in accordance with local regulations. Empty containers or liners may retain some Residual waste

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

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.

APVMA Registration Number: 38692

Poison Schedule (Product) - Schedule 4

This SDS replaces version: Issued 18 April 2017

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 10

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

Benzyl alcohol (CAS 100-51-6)

10000 - 99999 TONNES See the regulation for additional

information.

Water for Injection (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.

Resricted 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 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

Country(s) or region	Inventory name	On inventory (yes/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

Issue date 18-April-2017 **Revision date** 22-March-2022

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while Disclaimer

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.

This document has undergone significant changes and should be reviewed in its entirety. **Revision information**