

Section 1 - Identification of the Material and Supplier

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Chemical nature:	Lincomycin is an antibiotic
Trade Name:	Lincomix Antibiotic Solution 300mg/mL
Product Use:	Antibiotic injection for the treatment of infections caused by micro-organisms sensitive to lincomycin
Creation Date:	January, 2005
This version issued:	1 October, 2016 and is valid for 5 years from this date

Section 2 - Hazards Identification

Appearance: Colorless liquid

Classification of the Substance or Mixture

GHS - Classification

Skin Sensitization: Category 1

Label Elements

Signal Word: Warning

Hazard Statements: H317 - May cause an allergic skin reaction

Precautionary Statements: P280 - Wear protective gloves/protective clothing/eye protection/face protection
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P272 - Contaminated work clothing should not be allowed out of the workplace
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P362 - Take off contaminated clothing and wash before reuse
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards

Short Term:

May cause eye, skin and respiratory tract irritation. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

Known Clinical Effects:

The most common adverse effects reported with clinical use were diarrhea, nausea, rash, and vomiting. Effects on blood and blood-forming

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organs have also occurred. This compound can cross the placenta in pregnant women. Secreted in human breast milk.

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3 - Composition/Information on Ingredients

Hazardous

Ingredients	CAS No	Conc, %	GHS Classification
Lincomycin Hydrochloride	859-18-7	2.5 – 30	Skin Sens.1 (H317)
Benzyl Alcohol	100-51-6	1	Acute Tox.4 (H302) Acute Tox.4 (H332)
Water	7732-18-5	*	Not Listed

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non-hazardous ingredients are also possible.

Section 4 - First Aid Measures

Description of First Aid Measures**Eye Contact:**

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact:

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion:

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation:

Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed**Symptoms and Effects of Exposure:**

For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions**Aggravated by Exposure:**

Individuals with a history of hypersensitivity to this material or other materials in its chemical class, individuals with other allergic conditions or diseases (asthma, eczema, etc.).

Indication of the Immediate Medical Attention and Special Treatment Needed**Notes to Physician:**

None

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Section 5 - Fire Fighting Measures

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Not flammable.

Advice for Fire-Fighters

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

Additional Information: This product is a nonflammable aqueous solution.

Section 6 - Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Section 7 - Handling and Storage

Precautions for Safe Handling

When handling, use appropriate personal protective equipment (see Section 8). Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Avoid accidental injection. Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Keep in tightly sealed containers in a well-ventilated area away from heat and sources of ignition. Store as directed by product packaging.

Specific end use(s): No data available

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Section 8 - Exposure Controls and Personal Protection

Control Parameters

Lincomycin Hydrochloride

Zoetis OEL TWA 8-hr 100µg/m³

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section. General room ventilation is adequate unless the process generates dust, mist or fumes.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

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

Eyes:

Wear safety glasses or goggles if eye contact is possible.

Skin:

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

Respiratory protection:

If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Section 9 - Physical and Chemical Properties:

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

Solvent Solubility: No data available

Water Solubility: No data available

Solubility: Soluble: Water

pH: No data available

Melting/Freezing Point (°C): No data available

Boiling Point (°C): No data available

Partition Coefficient: (Method, pH, Endpoint, Value)
No data available

Lincomycin Hydrochloride

Measured 6-8 Log D 2.55

Decomposition Temperature (°C): No data available

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

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Section 10 - Stability and Reactivity

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use
Possibility of Hazardous Reactions	
Oxidizing Properties:	None
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

Section 11 - Toxicological Information

Information on Toxicological Effects

General Information:	Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation. Routes of exposure: eye contact, skin contact
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Acute Toxicity: (Species, Route, End Point, Dose)

Lincomycin Hydrochloride

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

Benzyl Alcohol

Rat	Oral	LD ₅₀	1230 mg/kg
Rat	Para-periosteal	LD ₅₀	53mg/kg
Rat	Inhalation	LC ₅₀	>4.178mg/L

Acute Toxicity Comments:	A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.
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Inhalation Acute Toxicity	Allergic reactions might occur based on effects of the individual components.
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Irritation / Sensitization: (Study Type, Species, Severity)

Benzyl Alcohol

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

Irritation / Sensitization Comments:	May cause eye irritation based on components.
Skin Irritation / Sensitization	May cause skin irritation based on components. May cause allergic reactions in susceptible individuals.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Lincomycin Hydrochloride

30 Day(s)	Rat	Oral 300 mg/kg/day	NOAEL	No effects at maximum dose
30 Day(s)	Rat	Subcutaneous 60 mg/kg/day	NOAEL	None identified
3 Month(s)	Rat	Oral 300 mg/kg/day	NOAEL	None identified
3 Month(s)	Dog	Oral 400 mg/kg/day	LOAEL	None identified
6 Month(s)	Dog	Oral 100 mg/kg/day	NOAEL	Immune system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

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Lincomycin Hydrochloride

2 Generation Reproductive Toxicity	Rat	Oral	100 mg/kg	LOAEL	Fetotoxicity
Prenatal & Postnatal Development	Rat	Oral	100 mg/kg	NOEL	Not Teratogenic
Fertility and Embryonic Development	Rat	Subcutaneous	75 mg/kg/day	NOAEL	No effects at maximum dose
Embryo / Fetal Development	Rat	Subcutaneous	300 mg/kg/day	NOAEL	Not Teratogenic
Peri-/Postnatal Development	Rat	Subcutaneous	30 mg/kg/day	NOAEL	No effects at maximum dose

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**Lincomycin Hydrochloride**

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

Carcinogen Status:

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

Section 12 - Ecological Information**Environmental Overview:**

Environmental properties of the formulation have not been investigated. Releases to the environment should be avoided. See aquatic toxicity data for individual components below:

Toxicity:**Aquatic Toxicity: (Species, Method, End Point, Duration, Result)****Lincomycin Hydrochloride**

<i>Lepomis macrochirus</i> (Bluegill Sunfish)	ASTM	LC50	96 Hours	>980 mg/L
<i>Daphnia magna</i> (Water Flea)	ASTM	EC50	48 Hours	>900 mg/L
<i>Anabaena flos-aquae</i> (Cyanobacteria)	OECD	EC50	72 Hours	0.03 mg/L
<i>Salmo gairdneri</i> (Trout)	ASTM	LC50	96 Hours	>980 mg/L

Benzyl Alcohol

<i>Pimephales promelas</i> (Fathead Minnow)	EPA	LC50	96 Hours	460 mg/L
<i>Daphnia magna</i> (Water Flea)	OECD	EC50	48 Hours	230 mg/L
<i>Pseudokirchneriella subcapitata</i> (Green Alga)	OECD	EC50	72 Hours	500 mg/L

Aquatic Toxicity Comments:

A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)**Benzyl Alcohol**

<i>Daphnia magna</i> (Water Flea)	OECD	21 Day(s)	EC50 66 mg/L	Reproduction
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Persistence and Degradability:**Benzyl Alcohol**

OECD Activated sludge	Ready	92% After	14 Day(s)	Ready
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Bio-accumulative Potential:**Lincomycin Hydrochloride**

Measured	6-8	Log D	2.55
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Mobility in Soil:

No data available

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Section 13 - Disposal Considerations

Disposal: Dispose of empty container by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled sharps container.

Section 14 - Transport Information

The following refers to all modes of transportation unless specified below.

Not regulated for transport under IATA, ADG or IMDG regulations

Section 15 - Regulatory Information

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Poison Schedule: Schedule 4

Lincomycin Hydrochloride

Australia (AICS): Present

Benzyl Alcohol

Australia (AICS): Present

Water

Australia (AICS): Present

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations. The following ingredient: Lincomycin is mentioned in the SUSMP.

Section 16 - Other Information

This MSDS contains only safety-related information. For other data see product literature.

Acronyms:

ADG Code	Australian Code for the Transport of Dangerous Goods by Road and Rail, 7th Edition
AICS	Australian Inventory of Chemical Substances
CAS number	Chemical Abstracts Service Registry Number
Hazchem Number	Emergency action code of numbers and letters that provide information to emergency services especially firefighters
IARC	International Agency for Research on Cancer
SWA	Safe Work Australia, formerly ASCC and NOHSC
NOS	Not otherwise specified
NTP	National Toxicology Program (USA)
R-Phrase	Risk Phrase
SUSMP	Standard for the Uniform Scheduling of Medicines & Poisons
UN Number	United Nations Number

This version issued: 1 October 2016 and is valid for 5 years from this date

Supersedes: Revision issued July 2016

Revision History:

Date of Revision	Reason
17 Nov 2014	Update to GHS
01 Jul 2016	Revision for consistency with Zoetis organisation

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01 Oct 2016	Minor formatting changes

Contact Points:

Zoetis	1800 814 883
Police and Fire Brigade:	Dial 000

If ineffective:**Dial Poisons Information Centre
(13 11 26 from anywhere in Australia)**

THIS SDS SUMMARISES OUR CURRENT AND BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION ABOUT THE PRODUCT DETAILED IN THIS SDS, AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE FOR THE RECOMMENDED USE. EACH USER OF THE PRODUCT MUST REVIEW THIS SDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THEIR OWN WORKPLACE. IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT ZOETIS.

Please read all labels carefully before using product.

This SDS is prepared in accord with the SWA document "Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice" (December 2011)

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