

# SAFETY DATA SHEET



Revision date: 23-Mar-2015

Version: 4.2

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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Lincomycin Hydrochloride Injectable

**Trade Name:** Lincocin®; LINCOMIX®; ALBIOTIC®

**Synonyms:** Lincocin® Sterile Solution, LINCOMIX® Injectable, LINCOMIX® 100 Injectable, Lincocine 100 injectable; Lincocin 100 mg/ml; Albiotic 100 mg/ml, Lincocin VET

**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Veterinary product used as antibiotic agent

**Restrictions on Use:** Not for human use

### Details of the Supplier of the Safety Data Sheet

Zoetis Inc.  
100 Campus Drive, P.O. Box 651  
Florham Park, New Jersey 07932 (USA)  
Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896  
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.  
Mercuriusstraat 20  
1930 Zaventem  
Belgium

**Emergency telephone number:**  
CHEMTREC (24 hours): 1-800-424-9300  
**Contact E-Mail:** VMIPSrecords@zoetis.com

**Emergency telephone number:**  
International CHEMTREC (24 hours): +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

**Appearance:** Colorless liquid

### Classification of the Substance or Mixture

#### GHS - Classification

Skin Sensitization: Category 1

#### EU Classification:

EU Indication of danger: Irritant

EU Symbol: Xi

EU Risk Phrases:  
R43 - May cause sensitization by skin contact.

### Label Elements

**Signal Word:** Warning

**Hazard Statements:** H317 - May cause an allergic skin reaction

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

### Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

### 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.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Lincomycin Hydrochloride	859-18-7	212-726-7	Xi;R43	Skin Sens.1 (H317)	2.5 - 30
Benzyl Alcohol	100-51-6	202-859-9	Xn; R20/22	Acute Tox.4 (H302) Acute Tox.4 (H332)	1

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Water	7732-18-5	231-791-2	Not Listed	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.

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For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

#### Description of First Aid Measures

<b>Eye Contact:</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<b>Skin Contact:</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion:</b>	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.
<b>Inhalation:</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

#### Most Important Symptoms and Effects, Both Acute and Delayed

<b>Symptoms and Effects of Exposure:</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
<b>Medical Conditions Aggravated by Exposure:</b>	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

<b>Notes to Physician:</b>	None
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### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture

<b>Hazardous Combustion Products:</b>	Formation of toxic gases is possible during heating or fire.
<b>Fire / Explosion Hazards:</b>	Not flammable.

#### Advice for Fire-Fighters

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

**Additional Information:** This product is a nonflammable aqueous solution.

### 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

<b>Measures for Cleaning / Collecting:</b>	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
<b>Additional Consideration for Large Spills:</b>	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

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### 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

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### Lincomycin Hydrochloride

Zoetis OEL TWA 8-hr 100µg/m<sup>3</sup>

#### Benzyl Alcohol

Bulgaria OEL - TWA 5.0 mg/m<sup>3</sup>

Czech Republic OEL - TWA 40 mg/m<sup>3</sup>

Finland OEL - TWA 10 ppm

45 mg/m<sup>3</sup>

Latvia OEL - TWA 5 mg/m<sup>3</sup>

Lithuania OEL - TWA 5 mg/m<sup>3</sup>

Poland OEL - TWA 240 mg/m<sup>3</sup>

#### 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Liquid	<b>Color:</b>	Colorless
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**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

### 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.

### 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

#### 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 LD50 1230 mg/kg

Rat Para-periosteal LD50 53mg/kg

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### 11. TOXICOLOGICAL INFORMATION

Rat Inhalation LC50 >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.

**Inhalation Acute Toxicity** Allergic reactions might occur based on effects of the individual components.

#### 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))

##### **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) *Salmonella* Negative

Mammalian Cell Mutagenicity Mouse Lymphoma Negative

*In Vivo* 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.

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### 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

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:**

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. 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.

### 14. TRANSPORT INFORMATION

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

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Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

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

##### Canada - WHMIS: Classifications

##### WHMIS hazard class:

Class D, Division 2, Subdivision B

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.



##### Lincomycin Hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	212-726-7

##### Benzyl Alcohol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-859-9

##### Water

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

### 16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3



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Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled  
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction

Xi - Irritant  
Xn - Harmful

R43 - May cause sensitization by skin contact.  
R20/22 - Harmful by inhalation and if swallowed.

**Data Sources:** The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.  
Updated Section 2 - Hazard Identification. Updated Section 11 - Toxicology Information.

**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

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.

**End of Safety Data Sheet**