



MATERIAL SAFETY DATA SHEET

Revision date: 18-Mar-2008

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Animal Health
Pfizer Inc
235 East 42nd Street
New York, NY 10017
Poison Control Center Phone: 1-866-531-8896
Technical Services Phone: 1-800-366-5288

Pfizer Ltd,
Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

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

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Lincomycin Hydrochloride Injectable

Trade Name:	LINCOMIX® Injectable; Lincocin®
Synonyms:	Lincomix®25; Lincomix®100; Lincomix®300; Lincomycin Hydrochloride Sterile Solution; Lincomycin Hydrochloride Injection, USP
Chemical Family:	Mixture
Intended Use:	Veterinary product used as antibiotic agent
Restrictions on Use:	Not for human use

2. HAZARDS IDENTIFICATION

Appearance: Colorless liquid
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.

Additional Hazard Information:
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.

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.

EU Indication of danger: Irritant

EU Hazard Symbols:



EU Risk Phrases:

Australian Hazard Classification
(NOHSC):

R43 - May cause sensitization by skin contact.
Hazardous Substance, Non-Dangerous Goods.

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2. HAZARDS IDENTIFICATION

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings 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	Classification	%
Benzyl Alcohol	100-51-6	202-859-9	Xn;R20/22	*
Lincomycin Hydrochloride	859-18-7	212-726-7	Xi;R43	2.5 - 30

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

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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. Delayed effects may occur. For information on potential delayed effects, see Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media:

Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products:

Not determined

Fire Fighting Procedures:

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

Fire / Explosion Hazards:

No data available

6. ACCIDENTAL RELEASE MEASURES

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6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
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.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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.

7. HANDLING AND STORAGE

General Handling:	Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided.
Storage Conditions:	Store as directed by product packaging. Keep out of reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Benzyl Alcohol

Bulgaria OEL - TWA	= 5.0 mg/m ³ TWA
Czech Republic OEL - TWA	= 40 mg/m ³ TWA
Latvia OEL - TWA	= 5 mg/m ³ TWA
Lithuania OEL - TWA	= 5 mg/m ³ IPRV
Poland OEL - TWA	= 240 mg/m ³ NDS

Lincomycin Hydrochloride

Pfizer OEL TWA-8 Hr:	100 µg/m ³
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The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated. Refer to available public information for specific member state Occupational Exposure Limits.

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

Physical State:	Liquid	Color:	Colorless
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solubility:	Soluble: Water		

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9. PHYSICAL AND CHEMICAL PROPERTIES:

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Not determined
Incompatible Materials: No data available

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Benzyl Alcohol

Rat Oral LD50 1.23 g/kg
Rat Intravenous LD50 53 mg/kg

Lincomycin Hydrochloride

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

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.

Irritation / Sensitization: (Study Type, Species, Severity)

Benzyl Alcohol

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

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

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11. TOXICOLOGICAL INFORMATION

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.

12. ECOLOGICAL INFORMATION

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

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

Lincomycin Hydrochloride

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

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

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

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

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15. REGULATORY INFORMATION

EU Symbol: Xi
EU Indication of danger: Irritant

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

EU Safety Phrases:
S24 - Avoid contact with skin.
S37 - Wear suitable gloves.

OSHA Label:
WARNING
May cause allergic skin reaction.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision B



Benzyl Alcohol
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 202-859-9

Lincomycin Hydrochloride
Australia (AICS): Present
EU EINECS/ELINCS List 212-726-7

Water
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 mentioned in Section 3

R43 - May cause sensitization by skin contact.

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R20/22 - Harmful by inhalation and if swallowed.

Data Sources: Safety data sheets for individual ingredients. Publicly available toxicity information.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet