MATERIAL SAFETY DATA SHEET

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Lincomycin Hydrochloride Injection, USP

Trade Name: Lincocin® Injection
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: Liquid

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

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: Not classified

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

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	EU Classification	%
Lincomycin Hydrochloride	859-18-7	212-726-7	Xi;R43	0.5

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%

Benzyl Alcohol	100-51-6	202-859-9	Xn;R20/22	*
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: Not applicable

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). 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.

Storage Conditions: Store in a cool, dry place away from light. Keep out of reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Benzyl Alcohol

Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Poland OEL - TWA	Listed

Lincomycin Hydrochloride

Pfizer OEL TWA-8 Hr: 100 µg/m^3

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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

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

Physical State:	Liquid	**Color:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solubility: Soluble: Water

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.

10. STABILITY AND REACTIVITY

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)

Lincomycin Hydrochloride

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

Benzyl Alcohol

Rat	Oral	LD50	1230 mg/kg
Rat	Para-periosteal	LD50	53 mg/kg
Rat	Inhalation	LC50	46 mg/m^3

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

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

Lincomycin Hydrochloride

Bacterial Mutagenicity (Ames)	*Salmonella*	Negative
Mammalian Cell Mutagenicity	Mouse Lymphoma	Negative

11. TOXICOLOGICAL INFORMATION

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

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

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

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

15. REGULATORY INFORMATION

WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.
(Bad file name or number)

Benzyl Alcohol

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

Lincomycin Hydrochloride

Australia (AICS):	Listed
EU EINECS/ELINCS List	212-726-7

Water

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
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.
R20/22 - Harmful by inhalation and if swallowed.

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

Reasons for Revision: Not applicable

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

Pfizer Inc believes that the information contained in this Material 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