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,
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 Capsules

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

2. HAZARDS IDENTIFICATION

Appearance: Blue capsules ; white powder
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.

Additional Hazard Information:
Short Term: 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 Classification
EU Indication of danger: Irritant

EU Hazard Symbols:

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

Australian Hazard Classification (NOHSC): 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	41
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*
Magnesium Stearate	557-04-0	209-150-3	OEL	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Lactose Monohydrate	64044-51-5	Not listed	Not Listed	*
Gelatin	9000-70-8	232-554-6	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.

Notes to Physician: Epinephrine and supportive measures are recommended if the patient presents with anaphylactic symptoms.

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

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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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:	Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and 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. 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 at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Lincomycin Hydrochloride

Pfizer OEL TWA-8 Hr:	100 µg/m^3

Talc (non-asbestiform)

ACGIH Threshold Limit Value (TWA)	2 mg/m^3 TWA
ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	2.5 mg/m^3 containing no asbestos fibers
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Netherlands OEL - TWA	Listed
OSHA - Final PELs - Table Z-3 Mineral D:	TWA-20 mppcf
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

Magnesium Stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m^3 TWA
Australia TWA	10 mg/m^3
Belgium OEL - TWA	Listed

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

The exposure limit(s) listed for solid components are only relevant if dust 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:	Capsule	**Color:**	Blue
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Chemical 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)

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

11. TOXICOLOGICAL INFORMATION

Talc (non-asbestiform)
Rat Oral LD50 > 1600 mg/kg

Lactose Monohydrate
Rat Oral LD 50 29700 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.

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

Magnesium Stearate
13 Week(s) Rat Oral 1092 g/kg LOAEL Liver

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

Lactose Monohydrate
In Vitro Bacterial Mutagenicity (Ames) Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Talc (non-asbestiform)
IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation 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 Symbol: Xi
EU Indication of danger: Irritant

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

EU Safety Phrases:
S22 - Do not breathe dust.
S24 - Avoid contact with skin.
S37 - Wear suitable gloves.

OSHA Label:
WARNING
May cause allergic skin reaction.

Canada - WHMIS: Classifications

15. REGULATORY INFORMATION

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

Lincomycin Hydrochloride

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

Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	238-877-9

Lactose Monohydrate

Australia (AICS):	Listed

Gelatin

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	232-554-6

Magnesium Stearate

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	209-150-3

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R43 - May cause sensitization by skin contact.

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