



# MATERIAL SAFETY DATA SHEET

Revision date: 03-Mar-2008

Version: 2.0

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

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**Pfizer Pharmaceuticals Group**  
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**Emergency telephone number:**  
**ChemSafe (24 hours): +44 (0)208 762 8322**

### Material Name: Lincomycin Hydrochloride Capsules

<b>Trade Name:</b>	Lincocin
<b>Chemical Family:</b>	Mixture
<b>Intended Use:</b>	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 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.

**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.

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## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Lincomycin Hydrochloride	859-18-7	212-726-7	Xi;R43	41
Talc (non-asbestiform)	14807-96-6	238-877-9 EEC No. 456-230-0	Not Listed	*
Magnesium Stearate	557-04-0	209-150-3	Not Listed	*

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

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**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.

**Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Lincomycin Hydrochloride  
Pfizer OEL TWA-8 Hr: 100 µg/m<sup>3</sup>

Talc (non-asbestiform)  
ACGIH Threshold Limit Value (TWA) = 2 mg/m<sup>3</sup> TWA particulate matter containing no asbestos and <1% crystalline silica  
Listed

ACGIH OELs - Notice of Intended Changes

Australia TWA = 2.5 mg/m<sup>3</sup> TWA containing no asbestos fibers

Austria OEL - MAKs = 2 mg/m<sup>3</sup> MAK asbestos-free fibers

Belgium OEL - TWA = 2 mg/m<sup>3</sup> TWA

Bulgaria OEL - TWA = 1.0 f/cm<sup>3</sup> TWA containing <2% uncombined crystalline silicon dioxide

Czech Republic OEL - TWA = 3.0 mg/m<sup>3</sup> TWA  
= 6.0 mg/m<sup>3</sup> TWA  
= 10 mg/m<sup>3</sup> TWA  
= 2.0 mg/m<sup>3</sup> TWA

Denmark OEL - TWA = 0.3 fiber/cm<sup>3</sup> TWA

Estonia OEL - TWA = 0.5 mg/m<sup>3</sup> TWA  
= 1 mg/m<sup>3</sup> TWA

Finland OEL - TWA = 0.5 fibers/cm<sup>3</sup> TWA  
= 5 mg/m<sup>3</sup> TWA

Greece OEL - TWA = 10 mg/m<sup>3</sup> TWA  
= 2 mg/m<sup>3</sup> TWA

Hungary OEL - TWA = 2 mg/m<sup>3</sup> TWA

Ireland OEL - TWAs = 0.8 mg/m<sup>3</sup> TWA  
= 10 mg/m<sup>3</sup> TWA

Netherlands OEL - TWA = 1 mg/m<sup>3</sup> MAC

OSHA - Final PELs - Table Z-3 Mineral D: = 20 mppcf TWA

Poland OEL - TWA = 1.0 mg/m<sup>3</sup> NDS  
= 4.0 mg/m<sup>3</sup> NDS

Portugal OEL - TWA = 2 mg/m<sup>3</sup> TWA

Romania OEL - TWA = 2 mg/m<sup>3</sup> TWA

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Slovakia OEL - TWA	= 10 mg/m <sup>3</sup> TWA = 2 mg/m <sup>3</sup> TWA
Slovenia OEL - TWA	= 2 mg/m <sup>3</sup> TWA
Spain OEL - TWA	= 2 mg/m <sup>3</sup> VLA-ED this value is for the particulated matter that is free from asbestos and contains less than 1% of crystalline silica
Sweden OEL - TWAs	= 1 mg/m <sup>3</sup> LLV = 2 mg/m <sup>3</sup> LLV

## Magnesium Stearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m <sup>3</sup> TWA	except stearates of toxic metals
Australia TWA	= 10 mg/m <sup>3</sup> TWA	
Belgium OEL - TWA	= 10 mg/m <sup>3</sup> TWA	
Ireland OEL - TWAs	= 10 mg/m <sup>3</sup> TWA	except lead stearate
Lithuania OEL - TWA	= 3 mg/m <sup>3</sup> IPRV	
Portugal OEL - TWA	= 10 mg/m <sup>3</sup> TWA	does not include stearates of toxic metals
Spain OEL - TWA	= 10 mg/m <sup>3</sup> VLA-ED	not including stearates of toxic metals
Sweden OEL - TWAs	= 5 mg/m <sup>3</sup> LLV	

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.

## Personal Protective Equipment:

<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	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>	Capsule	<b>Color:</b>	Blue
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

## 10. STABILITY AND REACTIVITY

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

## 11. TOXICOLOGICAL INFORMATION

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

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

#### 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

#### 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

#### 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 (Not Classifiable)

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### 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

<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

**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.

### 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.

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## Canada - WHMIS: Classifications

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



### Lincomycin Hydrochloride

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

### Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	238-877-9 EEC No. 456-230-0

### Magnesium Stearate

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

### Gelatin

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

### Lactose Monohydrate

Australia (AICS):	Present
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## 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:** Added Pfizer OEL (Section 8). Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

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

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**End of Safety Data Sheet**