



MATERIAL SAFETY DATA SHEET

Revision date: 18-Mar-2008

Version: 2.0

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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,
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CT13 9NJ
United Kingdom
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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 Tablets

Trade Name:	Lincocin®
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as antibiotic agent
Restrictions on Use:	Not for human use

2. HAZARDS IDENTIFICATION

Appearance: White tablet
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:

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

Australian Hazard Classification (NOHSC):

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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2. HAZARDS IDENTIFICATION

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Lincomycin Hydrochloride	859-18-7	212-726-7	Xi;R43	83
Sucrose	57-50-1	200-334-9	Not Listed	*
Corn Starch	9005-25-8	232-679-6	Not Listed	*
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	%
Water, purified	7732-18-5	231-791-2	Not Listed	*
Sorbic acid	110-44-1	203-768-7	Not Listed	*
Sorbitol solution	50-70-4	200-061-5	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

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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 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.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Lincomycin Hydrochloride
Pfizer OEL TWA-8 Hr:

100 µg/m³

Sucrose

ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA
Australia TWA	= 10 mg/m ³ TWA
Belgium OEL - TWA	= 10 mg/m ³ TWA
Bulgaria OEL - TWA	= 10.0 mg/m ³ TWA
Estonia OEL - TWA	= 10 mg/m ³ TWA
France OEL - TWA	= 10 mg/m ³ VME
Ireland OEL - TWAs	= 10 mg/m ³ TWA
Lithuania OEL - TWA	= 10 mg/m ³ IPRV
OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA total
	= 5 mg/m ³ TWA
Portugal OEL - TWA	= 10 mg/m ³ TWA
Slovakia OEL - TWA	= 6 mg/m ³ TWA
Spain OEL - TWA	= 10 mg/m ³ VLA-ED

Corn Starch

ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA
Australia TWA	= 10 mg/m ³ TWA
Belgium OEL - TWA	= 10 mg/m ³ TWA
Bulgaria OEL - TWA	= 10.0 mg/m ³ TWA
Czech Republic OEL - TWA	= 4.0 mg/m ³ TWA
Greece OEL - TWA	= 10 mg/m ³ TWA
	= 5 mg/m ³ TWA
Ireland OEL - TWAs	= 10 mg/m ³ TWA
	= 4 mg/m ³ TWA
OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA total
	= 5 mg/m ³ TWA
Portugal OEL - TWA	= 10 mg/m ³ TWA
Spain OEL - TWA	= 10 mg/m ³ VLA-ED

Talc (non-asbestiform)

ACGIH Threshold Limit Value (TWA)	= 2 mg/m ³ TWA particulate matter containing no asbestos and <1% crystalline silica
ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	= 2.5 mg/m ³ TWA containing no asbestos fibers
Austria OEL - MAKs	= 2 mg/m ³ MAK asbestos-free fibers
Belgium OEL - TWA	= 2 mg/m ³ TWA
Bulgaria OEL - TWA	= 1.0 f/cm ³ TWA containing <2% uncombined crystalline silicon dioxide
	= 3.0 mg/m ³ TWA
	= 6.0 mg/m ³ TWA
Czech Republic OEL - TWA	= 10 mg/m ³ TWA
	= 2.0 mg/m ³ TWA
Denmark OEL - TWA	= 0.3 fiber/cm ³ TWA
Estonia OEL - TWA	= 0.5 mg/m ³ TWA
	= 1 mg/m ³ TWA
Finland OEL - TWA	= 0.5 fibers/cm ³ TWA
	= 5 mg/m ³ TWA

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Greece OEL - TWA	= 10 mg/m ³ TWA
	= 2 mg/m ³ TWA
Hungary OEL - TWA	= 2 mg/m ³ TWA
Ireland OEL - TWAs	= 0.8 mg/m ³ TWA
	= 10 mg/m ³ TWA
Netherlands OEL - TWA	= 1 mg/m ³ MAC
OSHA - Final PELs - Table Z-3 Mineral D:	= 20 mppcf TWA
Poland OEL - TWA	= 1.0 mg/m ³ NDS
	= 4.0 mg/m ³ NDS
Portugal OEL - TWA	= 2 mg/m ³ TWA
Romania OEL - TWA	= 2 mg/m ³ TWA
Slovakia OEL - TWA	= 10 mg/m ³ TWA
	= 2 mg/m ³ TWA
Slovenia OEL - TWA	= 2 mg/m ³ TWA
Spain OEL - TWA	= 2 mg/m ³ 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 ³ LLV
	= 2 mg/m ³ LLV

Magnesium Stearate

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

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.

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9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Tablet	Color:	White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

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)

Sorbic acid

Rat	Oral	LD50	7360 mg/kg
Mouse	Oral	LD50	3200 mg/kg

Sorbitol solution

Rat	Oral	LD50	15,900 mg/kg
Mouse	Oral	LD50	17,800 mg/kg

Talc (non-asbestiform)

Rat	Oral	LD50	> 1600 mg/kg
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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

Sucrose

Rat	Oral	LD50	29.7 g/kg
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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)

Magnesium Stearate

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

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11. TOXICOLOGICAL INFORMATION

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)	<i>Salmonella</i>	Negative
Mammalian Cell Mutagenicity	Mouse Lymphoma	Negative
<i>In Vivo</i> 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)

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:

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

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<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.

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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:
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

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



Lincomycin Hydrochloride

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

Water, purified

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
REACH - Annex IV - Exemptions from the Present
obligations of Register:
EU EINECS/ELINCS List 231-791-2

Sorbic acid

Inventory - United States TSCA - Sect. 8(b) T
Australia (AICS): Present
EU EINECS/ELINCS List 203-768-7

Sucrose

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
REACH - Annex IV - Exemptions from the Present
obligations of Register:
EU EINECS/ELINCS List 200-334-9

Sorbitol solution

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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	200-061-5

Corn Starch

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

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

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 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

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Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet