



MATERIAL SAFETY DATA SHEET

Revision date: 30-Jul-2007

Version: 2.3

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
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Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Clindamycin Hydrochloride Capsules

Trade Name:	Cleocin; Dalacin
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance:	75 mg - Green 150 mg - Light Blue/Green 300 mg - Light Blue
Signal Word:	WARNING
Statement of Hazard:	May cause allergic reaction. May cause eye irritation
Additional Hazard Information:	
Short Term:	Active ingredient is not a skin irritant ; Not acutely toxic (based on animal data) .
Known Clinical Effects:	Adverse effects associated with the therapeutic use include gastrointestinal disturbances such as nausea, dyspepsia, and vomiting and gastrointestinal irritation. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.
EU Indication of danger:	Irritant
EU Hazard Symbols:	
EU Risk Phrases:	R36 - Irritating to eyes. R43 - May cause sensitization by skin contact.

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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	%
Clindamycin Hydrochloride	21462-39-5	244-398-6	Xi;R36-43	20-30.2
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	*
Corn Starch	9005-25-8	232-679-6	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Lactose	63-42-3	200-559-2	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.

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.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire. May include oxides of carbon, nitrogen, sulfur, and chlorine.

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

Fire / Explosion Hazards: Not applicable

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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).
Storage Conditions:	Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.
Storage Temperature:	20 - 25°C (68-77°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Clindamycin Hydrochloride	
Pfizer OEL TWA-8 Hr:	100 µg/m ³
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
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

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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	

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

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

Analytical Method: Analytical method available for clindamycin. Contact Pfizer Inc for further information.

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:	Capsule	Color:	Green (75 mg), Light blue / green (150 mg), light blue (300 mg)
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

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)

Clindamycin Hydrochloride

Rat	Oral	LD 50	2618 mg/kg
Rat	Intraperitoneal	LD 50	279 mg/kg
Rat	Subcutaneous	LD 50	891 mg/kg
Mouse	Oral	LD 50	1479 mg/kg
Mouse	Intravenous	LD 50	143 mg/kg

Lactose

Rat	Oral	LD50	> 10 g/kg
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Talc (non-asbestiform)

Rat	Oral	LD50	> 1600 mg/kg
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Magnesium stearate

Rat	Oral	LD50	> 2000 mg/kg
Rat	Inhalation	LC50	> 2000 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)

Clindamycin Hydrochloride

Eye Irritation	Rat	No effect
Eye Irritation	Rabbit	Moderate
Skin Irritation	Rat	No effect

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Clindamycin Hydrochloride

6 Month(s)	Rat	Oral	600 mg/kg/day	NOAEL	No effects at maximum dose
6 Month(s)	Dog	Oral	600 mg/kg/day	LOAEL	Gastrointestinal system

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1 Year(s) Rat Oral 300 mg/kg/day NOAEL No effects at maximum dose
1 Month(s) Dog Oral 300 mg/kg/day NOAEL No effects at maximum dose

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Clindamycin Hydrochloride

Reproductive & Fertility Rat Oral 300 mg/kg/day NOAEL Fertility
Embryo / Fetal Development Mouse Oral 600 mg/kg/day NOAEL Not Teratogenic
Embryo / Fetal Development Rat Oral 600 mg/kg/day NOAEL Not Teratogenic
Embryo / Fetal Development Rat Subcutaneous 250 mg/kg/day NOAEL Not Teratogenic

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

Clindamycin Hydrochloride

Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vitro Micronucleus 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 have not been thoroughly investigated. Releases to the environment should be avoided.

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

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EU Risk Phrases:

R36 - Irritating to eyes.
R43 - May cause sensitization by skin contact.

EU Safety Phrases:

S22 - Do not breathe dust.
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S37 - Wear suitable gloves.

OSHA Label:

WARNING
May cause allergic reaction.
May cause eye irritation

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, and Subdivision B.



Clindamycin Hydrochloride

EU EINECS/ELINCS List 244-398-6

Lactose

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 200-559-2

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

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

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16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R36 - Irritating to eyes.

R43 - May cause sensitization by skin contact.

Reasons for Revision:

Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 8 - Exposure Controls / Personal Protection.

Prepared by:

Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet