



MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 1.1

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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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Chloramphenicol Capsules 500 mg

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Magnesium Stearate	557-04-0	209-150-3	*
Chloramphenicol	56-75-7	200-287-4	80

Ingredient	CAS Number	EU EINECS List	%
Sodium Lauryl Sulfate	151-21-3	205-788-1	*
Lactose	63-42-3	200-559-2	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: White and Gray capsules
Signal Word: DANGER

Statement of Hazard: Possible carcinogen and mutagen.
May cause adverse effects on blood forming organs.
Possible risk of harm to the unborn child.
May cause reproductive system effects.

Additional Hazard Information:

Short Term: Not an eye irritant ; Not acutely toxic (based on animal data) Accidental ingestion may cause effects similar to those seen in clinical use.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on the hematological and reproductive systems.

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Known Clinical Effects: The most serious adverse reaction seen with the use of chloramphenicol is reversible, dose related, bone marrow depression. Serious and fatal blood effects (aplastic anemia, hypoplastic anemia, thrombocytopenia, and granulocytopenia) have also occurred after chloramphenicol treatment. The aplastic anemia seen from treatment may terminate in leukemia. GI and CNS effects have occurred infrequently and hypersensitivity reactions have been reported rarely. Ophthalmic use of chloramphenicol has resulted in optic neuritis, impaired central vision, and injury to the optic and peripheral nerves. Prolonged treatment may result in optic neuropathy. Sensitization, manifested as periocular and periauricular dermatitis, has also been reported.

EU Indication of danger: T - Toxic

EU Hazard Symbols:



EU Risk Phrases:

R45 - May cause cancer.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.
R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.
R68 - Possible risk of irreversible effects.
Hazardous Substance.

Australian Hazard Classification (NOHSC):

**Additional Information:
Note:**

For a more detailed discussion of potential health hazards and toxicity see Section 11. This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention. Flush eye(s) immediately with plenty of water.

Skin Contact: Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention. Rinse immediately with plenty of water for at least 15 minutes

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person. Drink 1 or 2 glasses of water.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, oxides of nitrogen and hydrogen chloride.

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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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:** If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.
- Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Magnesium Stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

Chloramphenicol

Pfizer OEL TWA-8 Hr: 0.5 mg/m³

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

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

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

- Hands:** Not required for the normal use of this product. Wear protective gloves when working with large quantities.
- Eyes:** Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
- Skin:** Not required for the normal use of this product. Wear protective clothing when working with large quantities.
- Respiratory protection:** Not required for the normal use of this product. 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:	Crystalline solid	Color:	White and Gray
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Water solubility:	2.5 mg/ml		

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10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Keep away from excessive heat and flames.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.
Hazardous Decomposition Products: When heated to decomposition this compound emits very toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and hydrogen chloride gas.
Polymerization: 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)

Sodium Lauryl Sulfate

Rat Oral LD 50 1288 mg/kg
Rat Intraperitoneal LD 50 210 mg/kg

Lactose

Rat Oral LD50 > 10 g/kg

Chloramphenicol

Mouse Oral LD50 2300 mg/kg
Mouse Oral LD50 1500 mg/kg
Rat Oral LD50 2500 mg/kg
Rat (M/F) Intravenous LD 50 170/171 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.

Irritation / Sensitization: (Study Type, Species, Severity)

Chloramphenicol

Eye Irritation Rabbit Non-irritating

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

Sodium Lauryl Sulfate

3 Day(s) Rat Oral 75 mg/kg LOAEL Liver, Blood

Magnesium Stearate

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

Chloramphenicol

14 Day(s) Dog Oral 75 mg/kg/day NOAEL Blood
60 Day(s) Rat Oral 60 mg/kg LOAEL None identified
14 Day(s) Mouse Oral 33600 mg/kg LOAEL Liver

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

Chloramphenicol

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Reproductive & Fertility-Males	Rat	100 mg/kg/day	NOAEL	Fertility
Embryo / Fetal Development	Rat	Oral 500 mg/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Mouse	Oral 500 mg/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rabbit	Oral 500 mg/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rat	Oral 23 g/kg	LOEL	Teratogenic

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

Chloramphenicol

Bacterial Mutagenicity (Ames)	Bacteria	Negative
Direct DNA Damage	Rat Hepatocyte	Positive
<i>In Vitro</i> Micronucleus	Mouse Lymphoma	Positive
Chromosome Aberration	Human Lymphocytes	Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Chloramphenicol

104 Week(s)	Mouse	Oral	500 mg/L/day	NOAEL	Lymphatic system
104 Week(s)	Mouse	Oral	500 mg/L/day	LOAEL	Lymphatic system, Liver

Carcinogen Status: See below

Chloramphenicol

IARC:	Group 2A
NTP:	Listed
OSHA:	Present

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Indication of danger: T - Toxic

EU Risk Phrases:

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R45 - May cause cancer.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.
R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.
R68 - Possible risk of irreversible effects.

EU Safety Phrases:

S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:

DANGER

Possible carcinogen and mutagen.
May cause adverse effects on blood forming organs.
Possible risk of harm to the unborn child.
May cause reproductive system effects.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A

Class D, Division 2, Subdivision B



Sodium Lauryl Sulfate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	205-788-1

Magnesium Stearate

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

Lactose

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

Chloramphenicol

California Proposition 65	carcinogen, initial date 10/1/89
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Present

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	200-287-4

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16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

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

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End of Safety Data Sheet