



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 2.1

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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CHEMTREC (24 hours): 1-800-424-9300

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

Material Name: Chloramphenicol Ophthalmic Ointment 1%

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	%
Chloramphenicol	56-75-7	200-287-4	1

Ingredient	CAS Number	EU EINECS List	%
Plastibase 30 W Sterile	Mixture	Not listed	*
Liquid paraffin	92062-35-6	295-550-3	*

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

3. HAZARDS IDENTIFICATION

Appearance: ointment
Signal Word: DANGER

Statement of Hazard: May cause cancer.
May cause genetic defects.
Suspected of damaging fertility or the unborn child.
May cause adverse effects on blood forming organs

Additional Hazard Information:
Short Term: Acute toxicity following ingestion is not expected.
Long Term: Repeated or prolonged exposure may cause effects similar to those seen in clinical use. 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 chlormaphenicol 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.

Note: 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.

Skin Contact: Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

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: Formation of toxic gases is possible during heating or fire.

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

Fire / Explosion Hazards: Not determined

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 spill with absorbent material. Clean spill area thoroughly.

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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: Avoid contact with eyes. Avoid contact with skin and clothing. Wash thoroughly after handling.

Storage Conditions: Keep in tightly closed containers away from heat and light. Store in a cool, dry, well-ventilated area.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Chloramphenicol
Pfizer OEL TWA-8 Hr: 0.5 mg/m³

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: Wear impervious gloves if skin contact is possible.
Eyes: Safety glasses or goggles
Skin: Wear protective clothing when working with large quantities.
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:	Ointment	Color:	Colorless
Molecular Formula:	Mixture	Molecular Weight:	Mixture

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: Will not occur .

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the active ingredient

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

Chloramphenicol

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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

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

Chloramphenicol

Eye Irritation Rabbit Non-irritating

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

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

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
In Vitro 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.

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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:
R45 - May cause cancer.

EU Safety Phrases:
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
DANGER
May cause cancer.
May cause genetic defects.
Suspected of damaging fertility or the unborn child.
May cause adverse effects on blood forming organs

Canada - WHMIS: Classifications

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



Liquid paraffin

Australia (AICS):	Present
EU EINECS List	295-550-3

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 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

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

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 a warranty of any kind, expressed or implied.

End of Safety Data Sheet