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

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium Stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>*</td>
</tr>
<tr>
<td>Chloramphenicol</td>
<td>56-75-7</td>
<td>200-287-4</td>
<td>80</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Lauryl Sulfate</td>
<td>151-21-3</td>
<td>205-788-1</td>
<td>*</td>
</tr>
<tr>
<td>Lactose</td>
<td>63-42-3</td>
<td>200-559-2</td>
<td>*</td>
</tr>
</tbody>
</table>

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.
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.

Australian Hazard Classification (NOHSC): Hazardous Substance.

Additional Information: 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.
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.


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
Molecular Formula: Mixture
Color: White and Gray
Molecular Weight: Mixture
Water solubility: 2.5 mg/ml
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 LD50 1288 mg/kg
- Rat Intraperitoneal LD50 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
Material Name: Chloramphenicol Capsules 500 mg
Revision date: 02-Jan-2007

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:
Material Name: Chloramphenicol Capsules 500 mg
Revision date: 02-Jan-2007

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
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