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 Ear Drops 0.5%

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium borate</td>
<td>1303-96-4</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Boric acid</td>
<td>10043-35-3</td>
<td>233-139-2</td>
<td>*</td>
</tr>
<tr>
<td>Phenylmercuric nitrate</td>
<td>55-68-5</td>
<td>200-242-9</td>
<td>0.002</td>
</tr>
<tr>
<td>Chloramphenicol</td>
<td>56-75-7</td>
<td>200-287-4</td>
<td>0.5</td>
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</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water for injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>###</td>
</tr>
</tbody>
</table>

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

3. HAZARDS IDENTIFICATION

Appearance: Liquid
Signal Word: DANGER

Statement of Hazard: Possible carcinogen

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.

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: 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 spill with absorbent material. 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: 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

Sodium borate
ACGIH Threshold Limit Value (TWA) = 2 mg/m³ TWA
ACGIH Threshold Limit Value (STEL) = 6 mg/m³ STEL
Australia TWA = 5 mg/m³ TWA

Boric acid
ACGIH Threshold Limit Value (TWA) = 2 mg/m³ TWA
ACGIH Threshold Limit Value (STEL) = 6 mg/m³ STEL

Phenylmercuric nitrate
ACGIH Threshold Limit Value (TWA) = 0.1 mg/m³ TWA
ACGIH - Skin Absorption Designation Skin - potential significant contribution to overall exposure by the cutaneous route
Australia TWA = 0.1 mg/m³ TWA

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


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: Not required for the normal use of this product. 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:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
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<tr>
<td>Color:</td>
<td>Colorless</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Water solubility:</td>
<td>100%</td>
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</table>
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)

**Boric acid**
- Rat Oral LD50 2500 mg/kg

**Chloramphenicol**
- Mouse Oral LD50 2300 mg/kg
- Mouse Oral LD50 1500 mg/kg
- Rat Oral LD50 2500 mg/kg
- Rat (M/F) Intravenous LD50 170/171 mg/kg

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

**Boric acid**
- Skin Irritation Human Mild

**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))

**Boric acid**
- Prenatal & Postnatal Development Rat Oral 74 mg/kg/day NOAEL Developmental toxicity
- Prenatal & Postnatal Development Rat Oral 55 mg/kg/day NOAEL Fetotoxicity
- Reproductive & Fertility-Males Mouse Oral 4500 ppm LOAEL Fertility

**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)
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: R45 - May cause cancer.

OSHA Label:
DANGER
Possible carcinogen

Canada - WHMIS: Classifications

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

<table>
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<tr>
<th>Substance</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS List</th>
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<tbody>
<tr>
<td>Sodium borate</td>
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<td>Boric acid</td>
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<tr>
<td>Phenylmercuric nitrate</td>
<td>CERCLA/SARA 313 Emission reporting = 1.0 % Supplier notification limit</td>
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16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. 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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