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

Material Name: Paromomycin Sulfate Capsules

- Trade Name: Humatin®
- Synonyms: Aminosidine Sulfate Capsules
- Chemical Family: Mixture
- Intended Use: Pharmaceutical product used as antibiotic agent

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
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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
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Appearance: Yellow capsules with a brown caplet.

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:
- Long Term: Animal studies indicate that this material may cause adverse effects on the kidneys and nervous system.
- Known Clinical Effects: Adverse effects associated with the therapeutic use include abdominal cramping, nausea and diarrhea. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. The following effects are based on a chemically-related material: contact dermatitis, effects on hearing.

EU Indication of danger: Not classified


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

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**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:**
Not available

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

**Fire / Explosion Hazards:**
Not applicable

**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). Releases to the environment should be avoided.

Storage Conditions: Protect from light. Protect from moisture. Store as directed by product packaging.

Storage Temperature: (15-25°C)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Colloidal silicon dioxide
- Australia TWA = 2 mg/m³ TWA
- Austria OEL - MAKs = 4 mg/m³ MAK
- Czech Republic OEL - TWA = 0.1 mg/m³ TWA
- Estonia OEL - TWA = 2 mg/m³ TWA
- Germany - TRGS 900 - TWAs = 4 mg/m³ TWA
- Ireland OEL - TWAs = 2.4 mg/m³ TWA
- = 6 mg/m³ TWA
- Latvia OEL - TWA = 1 mg/m³ TWA containing more than 70% SiO₂ (quartz)
= 2 mg/m³ TWA containing 10-70% SiO₂ (granite, mica)
= 4 mg/m³ TWA containing 2-10% SiO₂ (copper sulfate ores)
- OSHA - Final PELs - Table Z-3 Mineral D: (80)/(% SiO₂) mg/m³ TWA
= 20 mppcf TWA
- Slovakia OEL - TWA = 4.0 mg/m³ TWA
- Slovenia OEL - TWA = 4 mg/m³ TWA

Magnesium stearate
- ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
- Australia TWA = 10 mg/m³ TWA
- Belgium OEL - TWA = 10 mg/m³ TWA
- Ireland OEL - TWAs = 10 mg/m³ TWA except lead stearate
- Lithuania OEL - TWA = 3 mg/m³ IPRV
- Portugal OEL - TWA = 10 mg/m³ TWA does not include stearates of toxic metals
- Spain OEL - TWA = 10 mg/m³ VLA-ED not including stearates of toxic metals
- Sweden OEL - TWAs = 5 mg/m³ LLV

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

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Paromomycin sulfate
- Pfizer Occupational Exposure Band (OEB): OEB2 (control exposure to the range of >100µg/m³ to < 1000µg/m³)
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:** Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.

### 9. PHYSICAL AND CHEMICAL PROPERTIES:

<table>
<thead>
<tr>
<th>Physical State</th>
<th>Color</th>
<th>Molecular Formula</th>
<th>Molecular Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hard-gelatin Capsule</td>
<td>Yellow</td>
<td>Mixture</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

### 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.

**Conditions to Avoid:** Not determined

**Incompatible Materials:** bentonite, magnesium trisilicate, pectin, polysorbate 80

### 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)**

**Magnesium stearate**

- Rat Oral LD50 > 2000 mg/kg
- Rat Inhalation LC50 > 2000 mg/m³

**Paromomycin sulfate**

- Rat Oral LD50 21,620 mg/kg
- Mouse Oral LD50 23,500 mg/kg
- Rat Intravenous LD50 181 mg/kg
- Rat Intramuscular LD50 1200 mg/kg
- Rat Subcutaneous LD 50 870

**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.

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

**Paromomycin sulfate**

- 3 Month(s) Rabbit Subcutaneous 60 mg/kg/day LOAEL Kidney
- 3 Month(s) Rat Subcutaneous 200 mg/kg/day LOAEL Kidney
Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))
Paromomycin sulfate
Embryo / Fetal Development  Rat  Intramuscular  400 mg/kg/day  NOAEL  No effects at maximum dose

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)
Paromomycin sulfate
Bacterial Mutagenicity (Ames)  Salmonella , E. coli  Negative
In Vivo Micronucleus  Mouse  Negative
In Vitro Mammalian Cell Mutagenicity  Chinese Hamster Ovary (CHO) cells  Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))
Paromomycin sulfate
2 Year(s)  Rat  No route specified  Not carcinogenic
2 Year(s)  Dog  No route specified  Not carcinogenic

Carcinogen Status:
None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Colloidal silicon dioxide
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.

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15. REGULATORY INFORMATION

EU Symbol: None required
EU Indication of danger: Not classified

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Colloidal silicon dioxide
  Inventory - United States TSCA - Sect. 8(b): Present
  Australia (AICS): Present
  EU EINECS/ELINCS List: 231-545-4
  EEC No. 418-260-2

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

Paromomycin sulfate
  EU EINECS/ELINCS List: 215-031-7

16. OTHER INFORMATION

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Added Pfizer OEB (Section 8). Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology 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 warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet