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

Material Name: Paromomycin Sulfate Syrup

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

2. HAZARDS IDENTIFICATION

- Appearance: Opaque syrupy liquid
- 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. This product contains ethanol which can cause liver changes, central nervous system effects, and birth defects in the developing fetus.
  - 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

Contact E-Mail: pfizer-MSDS@pfizer.com
Emergency telephone number:
- CHEMTREC (24 hours): 1-800-424-9300
- ChemSafe (24 hours): +44 (0)208 762 8322

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

25MG/ML
## 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.

25MG/ML
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 breathing vapor or mist. 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: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit: = 2 mg/m³ Ceiling
Australia PEAK = 2 mg/m³ Peak
Austria OEL - MAKs = 2 mg/m³ MAK
Belgium OEL - TWA = 2 mg/m³ TWA
Bulgaria OEL - TWA = 2.0 mg/m³ TWA
Czech Republic OEL - TWA = 1 mg/m³ TWA
Finland OEL - TWA = 2 mg/m³ TWA
France OEL - TWA = 2 mg/m³ VME
Greece OEL - TWA = 2 mg/m³ TWA
Hungary OEL - TWA = 2 mg/m³ TWA
Latvia OEL - TWA = 0.5 mg/m³ TWA
Poland OEL - TWA = 0.5 mg/m³ NDS
Slovakia OEL - TWA = 2 mg/m³ TWA
Slovenia OEL - TWA = 2 mg/m³ TWA
Sweden OEL - TWAs = 1 mg/m³ LLV

Sodium bicarbonate
Latvia OEL - TWA = 5 mg/m³ TWA

Glycerol
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA
Belgium OEL - TWA = 10 mg/m³ TWA
Estonia OEL - TWA = 10 mg/m³ TWA
Finland OEL - TWA = 20 mg/m³ TWA
France OEL - TWA = 10 mg/m³ VME
Greece OEL - TWA = 10 mg/m³ TWA
Ireland OEL - TWAs = 10 mg/m³ TWA
Netherlands OEL - TWA = 10 mg/m³ MAC
OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
Poland OEL - TWA = 10 mg/m³ NDS
Portugal OEL - TWA = 10 mg/m³ TWA
Spain OEL - TWA = 10 mg/m³ VLA-ED

Sugar
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA
Belgium OEL - TWA = 10 mg/m³ TWA
Bulgaria OEL - TWA = 10.0 mg/m³ TWA
Estonia OEL - TWA = 10 mg/m³ TWA
France OEL - TWA = 10 mg/m³ VME
Ireland OEL - TWAs = 10 mg/m³ TWA
Lithuania OEL - TWA = 10 mg/m³ IPRV
OSHA - Final PELS - TWAs:
= 15 mg/m³ TWA total
= 5 mg/m³ TWA
Portugal OEL - TWA = 10 mg/m³ TWA
Slovakia OEL - TWA = 6 mg/m³ TWA
Spain OEL - TWA = 10 mg/m³ VLA-ED

ETHYL ALCOHOL
ACGIH Threshold Limit Value (TWA) = 1000 ppm TWA
Australia TWA = 1000 ppm TWA
= 1880 mg/m³ TWA
Austria OEL - MAKs = 1000 ppm MAK
= 1900 mg/m³ MAK
Belgium OEL - TWA = 1000 ppm TWA
= 1907 mg/m³ TWA
Bulgaria OEL - TWA = 1000.0 mg/m³ TWA
Czech Republic OEL - TWA = 1000 mg/m³ TWA
Denmark OEL - TWA = 1000 ppm TWA
= 1900 mg/m³ TWA
Estonia OEL - TWA = 1000 mg/m³ TWA
= 500 ppm TWA
Finland OEL - TWA = 1000 ppm TWA
= 1900 mg/m³ TWA
France OEL - TWA = 1000 ppm VME
= 1900 mg/m³ VME
Germany - TRGS 900 - TWAs = 500 ppm TWA
= 960 mg/m³ TWA
Greece OEL - TWA = 1000 ppm TWA
= 1900 mg/m³ TWA
Hungary OEL - TWA = 1900 mg/m³ TWA
Ireland OEL - TWAs = 1000 ppm TWA
= 1900 mg/m³ TWA
Latvia OEL - TWA = 1000 mg/m³ TWA
Lithuania OEL - TWA = 1000 mg/m³ IPRV
= 500 ppm IPRV
Netherlands OEL - TWA = 1000 mg/m³ MAC
= 500 ppm MAC
OSHA - Final PELS - TWAs:
= 1000 ppm TWA
= 1900 mg/m³ TWA
Poland OEL - TWA = 1900 mg/m³ NDS
Portugal OEL - TWA = 1000 ppm TWA
Romania OEL - TWA = 1000 ppm TWA
= 1900 mg/m³ TWA
Material Name: Paromomycin Sulfate Syrup
Revision date: 17-Oct-2007

The exposure limit(s) listed for solid components are only relevant if dust or mist 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 >100ug/m³ to < 1000ug/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>Syrupy liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color:</td>
<td>Opaque</td>
</tr>
<tr>
<td>Molecular Weight:</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)

25MG/ML


**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)

**Glycerol**
- Skin Irritation: Rabbit, Mild
- Eye Irritation: Rabbit, Mild

**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
- 3 Month(s) Mouse Subcutaneous 400 mg/kg/day LOAEL Kidney
- 3 Month(s) Cat Subcutaneous 50 mg/kg/day LOAEL Nervous System

**Propylparaben**
- 3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system
- 4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

**Glycerol**
- 28 Day(s) Rat Oral 16800 mg/kg LOAEL Endocrine system

**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

25MG/ML
Glycerol
Reproductive & Fertility-Males  Rat  Oral  100 mg/kg  LOEL  Fertility

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

Saccharin
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.

Saccharin
RCRA - U Series Wastes  waste number U202

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

25MG/ML
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.

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

SODIUM HYDROXIDE

CERCLA/SARA Hazardous Substances and their Reportable Quantities:
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 5
EU EINECS/ELINCS List 215-185-5

Sodium bicarbonate
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 205-633-8

Glycerol
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 200-289-5

Sugar
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
REACH - Annex IV - Exemptions from the obligations of Register:
EU EINECS/ELINCS List 200-334-9

ETHYL ALCOHOL

California Proposition 65 developmental toxicity, initial date 10/1/87 (when in alcoholic beverages)
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 200-578-6
16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R11 - Highly flammable.
R35 - Causes severe burns.

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