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

Product Identifier

Material Name: Paromomycin Sulfate Syrup

Trade Name: Humatin®; Gabbroral®
Synonyms: Aminosidine Sulfate Solution
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antibiotic agent

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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

Classification of the Substance or Mixture

GHS - Classification: Not classified as hazardous

EU Classification:
EU Indication of danger: Not classified

Label Elements

Hazard Statements: May form combustible dust concentrations in air

Other Hazards
No data available

Australian Hazard Classification (NOHSC):

Note:
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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

Hazardous
SAFETY DATA SHEET

Material Name: Paromomycin Sulfate Syrup
Revision date: 28-Mar-2015
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Version: 2.0

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
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<tr>
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<td>215-031-7</td>
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<td>215-185-5</td>
<td>C; R35</td>
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<td>Propylparaben</td>
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<tr>
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</tbody>
</table>

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.
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Special Hazards Arising from the Substance or Mixture

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

Fire / Explosion Hazards: Fine particles (such as mists) may fuel fires/explosions.

Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

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.

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

Precautions for Safe 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. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit: 2 mg/m³
Australia PEAK: 2 mg/m³
Austria OEL - MAKs: 2 mg/m³
Bulgaria OEL - TWA: 2.0 mg/m³
Czech Republic OEL - TWA: 1 mg/m³
Estonia OEL - TWA: 1 mg/m³
France OEL - TWA: 2 mg/m³
Greece OEL - TWA: 2 mg/m³
Hungary OEL - TWA: 2 mg/m³
Japan - OELs - Ceilings: 2 mg/m³
Latvia OEL - TWA: 0.5 mg/m³
OSHA - Final PELS - TWAs: 2 mg/m³

PZ01152
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Poland OEL - TWA** 0.5 mg/m³
**Slovakia OEL - TWA** 2 mg/m³
**Slovenia OEL - TWA** 2 mg/m³
**Sweden OEL - TWAs** 1 mg/m³
**Switzerland OEL - TWAs** 2 mg/m³

**Sodium bicarbonate**
- **Czech Republic OEL - TWA** 5 mg/m³
- **Latvia OEL - TWA** 5 mg/m³

**Glycerol**
- **Australia TWA** 10 mg/m³
- **Belgium OEL - TWA** 10 mg/m³
- **Czech Republic OEL - TWA** 10 mg/m³
- **Estonia OEL - TWA** 10 mg/m³
- **Finland OEL - TWA** 20 mg/m³
- **France OEL - TWA** 10 mg/m³
- **Germany (DFG) - MAK** 50 mg/m³
- **Greece OEL - TWA** 10 mg/m³
- **Ireland OEL - TWAs** 10 mg/m³
- **OSHA - Final PELS - TWAs:**
  - **Poland OEL - TWA** 15 mg/m³
  - **Spain OEL - TWA** 10 mg/m³
  - **Switzerland OEL - TWAs** 50 mg/m³

**Sugar**
- **ACGIH Threshold Limit Value (TWA)** 10 mg/m³
- **Australia TWA** 10 mg/m³
- **Belgium OEL - TWA** 10 mg/m³
- **Bulgaria OEL - TWA** 10.0 mg/m³
- **Estonia OEL - TWA** 10 mg/m³
- **France OEL - TWA** 10 mg/m³
- **Ireland OEL - TWAs** 10 mg/m³
- **Latvia OEL - TWA** 5 mg/m³
- **Lithuania OEL - TWA** 10 mg/m³
- **OSHA - Final PELS - TWAs:**
  - **Poland OEL - TWA** 15 mg/m³
  - **Portugal OEL - TWA** 10 mg/m³
  - **Spain OEL - TWA** 6 mg/m³
- **Switzerland OEL - TWA** 10 mg/m³

**ETHYL ALCOHOL**
- **ACGIH Threshold Limit Value (STEL)** 1000 ppm
- **Australia TWA** 1000 ppm
- **Austria OEL - MAKs** 1000 ppm
- **Belgium OEL - TWA** 1000 ppm
- **Bulgaria OEL - TWA** 1000 ppm
- **Czech Republic OEL - TWA** 1000 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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:
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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.

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<th>Country</th>
<th>OEL - TWA (ppm)</th>
<th>OEL - TWA (mg/m³)</th>
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<td>Latvia</td>
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<td>1900</td>
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<tr>
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<tr>
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</table>
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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>
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<th>Property</th>
<th>Value</th>
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10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Fine particles (such as mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
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 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.

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

Sugar
Rat Oral LD50 29700 mg/kg
Mouse Oral LD50 14000 mg/kg

Glycerol
Rat Oral LD50 12600 mg/kg

Sodium bicarbonate
Rat Oral LD50 4220 mg/kg
Mouse Oral LD50 3360 mg/kg
Rat Inhalation LC50 > 900 mg/m³

Methyl-p-hydroxybenzoate
Mouse Oral LD50 >8 g/kg
Rat Oral LD 50 2100 mg/kg

Propylparaben
Mouse Oral LD 50 6332 mg/kg
Mouse Sub-tenon injection (eye) LD 50 200 mg/kg

Paromomycin sulfate
Rat Oral LD50 21,620 mg/kg
Mouse Oral LD50 23,500 mg/kg
Rat Intravenous LD50 181mg/kg
Rat Intramuscular LD50 1200mg/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.
11. TOXICOLOGICAL INFORMATION

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

Glycerol
Skin Irritation  Rabbit  Mild
Eye Irritation  Rabbit  Mild

Sodium bicarbonate
Eye Irritation  Rabbit  Minimal
Skin Irritation  Rabbit  Slight

Methyl-p-hydroxybenzoate
Skin Irritation  Rabbit  Non-irritating
Eye Irritation  Rabbit  Slight
Skin Sensitization  Guinea Pig  Negative

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

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

Methyl-p-hydroxybenzoate
28 Day(s)  Rat  Oral  250 mg/kg/day  NOAEL  Gastrointestinal System, Spleen, Thymus

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

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

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

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

Methyl-p-hydroxybenzoate
Embryo / Fetal Development  Rabbit  Oral  300 mg/kg/day  NOEL  Maternal toxicity, Developmental toxicity

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)

Methyl-p-hydroxybenzoate
In Vivo Dominant Lethal Assay  Rat  Negative

Paromomycin sulfate
Bacterial Mutagenicity (Ames)  Salmonella , E. coli  Negative
11. TOXICOLOGICAL INFORMATION

In Vivo
Micronucleus: Mouse Negative

In Vitro
Mammalian Cell Mutagenicity: Chinese Hamster Ovary (CHO) cells Negative

In Vitro
Mammalian Cell Mutagenicity: Mouse Lymphoma 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 (Not Classifiable)

ETHYL ALCOHOL
IARC:
Group 1 (Carcinogenic to Humans)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Sodium bicarbonate
Daphnia magna (Water Flea) EC50 48 Hours 2350 mg/L
Lepomis macrochirus (Bluegill Sunfish) LC50 96 Hours 8250 mg/L
Gambusia affinis (Mosquitofish) LC50 96 Hours 7550 mg/L

Methyl-p-hydroxybenzoate
Orzias latipes (Japanese Rice Fish) OECD LC50 96 Hours 59.5 mg/L
Daphnia magna (Water Flea) ISO EC50 48 Hours 11.2 mg/L

Persistence and Degradability:
Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)
Methyl-p-hydroxybenzoate
OECD Activated sludge Ultimate (CO2 Evolution) 89% After 28 Day(s) Ready

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)
Paromomycin sulfate
Predicted 7.4 Log D -11.023

Mobility in Soil: No data available
13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

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

CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
EU EINECS/ELINCS List 215-031-7

SODIUM HYDROXIDE

CERCLA/SARA 313 Emission reporting Not Listed
CERCLA/SARA Hazardous Substances 1000 lb
and their Reportable Quantities: 454 kg
California Proposition 65 Not Listed
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

CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS)</th>
<th>EU EINECS/ELINCS List</th>
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<tbody>
<tr>
<td>Glycerol</td>
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<td>Present</td>
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<td>CERCLA/SARA 313 Emission reporting</td>
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15. REGULATORY INFORMATION

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16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor

C - Corrosive
F - Highly flammable

R11 - Highly flammable.
R35 - Causes severe burns.

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

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

Revision date: 28-Mar-2015

Prepared by: Product Stewardship Hazard Communication

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