MATERIAL SAFETY DATA SHEET

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

Pfizer Inc
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ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Paromomycin Sulfate Syrup

Trade Name:	Humatin®; Gabbroral®
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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Paromomycin sulfate	1263-89-4	215-031-7	Not Listed	3.57%
SODIUM HYDROXIDE	1310-73-2	215-185-5	C;R35	*
Sodium bicarbonate	144-55-8	205-633-8	Not Listed	*
Glycerol	56-81-5	200-289-5	Not Listed	*
Sugar	57-50-1	200-334-9	Not Listed	*
ETHYL ALCOHOL	64-17-5	200-578-6	F;R11	< 0.1%

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Water, purified	7732-18-5	231-791-2	Not Listed	*
Saccharin	81-07-2	201-321-0	Not Listed	*
Propylparaben	94-13-3	202-307-7	Not Listed	*
Methyl-p-hydroxybenzoate	99-76-3	202-785-7	Not Listed	*
Flavoring agents	Not assigned	Not listed	Not Listed	*

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

For the full text of the R phrases mentioned in this Section, see Section 16

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 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/m^3 Ceiling
Australia PEAK	= 2 mg/m^3 Peak
Austria OEL - MAKs	= 2 mg/m^3 MAK
Belgium OEL - TWA	= 2 mg/m^3 TWA
Bulgaria OEL - TWA	= 2.0 mg/m^3 TWA
Czech Republic OEL - TWA	= 1 mg/m^3 TWA
Finland OEL - TWA	= 2 mg/m^3 TWA
France OEL - TWA	= 2 mg/m^3 VME
Greece OEL - TWA	= 2 mg/m^3 TWA
Hungary OEL - TWA	= 2 mg/m^3 TWA
Latvia OEL - TWA	= 0.5 mg/m^3 TWA
Poland OEL - TWA	= 0.5 mg/m^3 NDS
Slovakia OEL - TWA	= 2 mg/m^3 TWA
Slovenia OEL - TWA	= 2 mg/m^3 TWA
Sweden OEL - TWAs	= 1 mg/m^3 LLV

Sodium bicarbonate

Latvia OEL - TWA	= 5 mg/m^3 TWA

Glycerol

ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA
Australia TWA	= 10 mg/m^3 TWA
Belgium OEL - TWA	= 10 mg/m^3 TWA
Estonia OEL - TWA	= 10 mg/m^3 TWA
Finland OEL - TWA	= 20 mg/m^3 TWA
France OEL - TWA	= 10 mg/m^3 VME
Greece OEL - TWA	= 10 mg/m^3 TWA
Ireland OEL - TWAs	= 10 mg/m^3 TWA
Netherlands OEL - TWA	= 10 mg/m^3 MAC
OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA total = 5 mg/m^3 TWA

Poland OEL - TWA	= 10 mg/m^3 NDS
Portugal OEL - TWA	= 10 mg/m^3 TWA
Spain OEL - TWA	= 10 mg/m^3 VLA-ED

Sugar

ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA
Australia TWA	= 10 mg/m^3 TWA
Belgium OEL - TWA	= 10 mg/m^3 TWA
Bulgaria OEL - TWA	= 10.0 mg/m^3 TWA
Estonia OEL - TWA	= 10 mg/m^3 TWA
France OEL - TWA	= 10 mg/m^3 VME
Ireland OEL - TWAs	= 10 mg/m^3 TWA
Lithuania OEL - TWA	= 10 mg/m^3 IPRV
OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA total = 5 mg/m^3 TWA
Portugal OEL - TWA	= 10 mg/m^3 TWA
Slovakia OEL - TWA	= 6 mg/m^3 TWA
Spain OEL - TWA	= 10 mg/m^3 VLA-ED

ETHYL ALCOHOL

ACGIH Threshold Limit Value (TWA)	= 1000 ppm TWA
Australia TWA	= 1000 ppm TWA = 1880 mg/m^3 TWA
Austria OEL - MAKs	= 1000 ppm MAK = 1900 mg/m^3 MAK
Belgium OEL - TWA	= 1000 ppm TWA = 1907 mg/m^3 TWA
Bulgaria OEL - TWA	= 1000.0 mg/m^3 TWA
Czech Republic OEL - TWA	= 1000 mg/m^3 TWA
Denmark OEL - TWA	= 1000 ppm TWA = 1900 mg/m^3 TWA
Estonia OEL - TWA	= 1000 mg/m^3 TWA = 500 ppm TWA
Finland OEL - TWA	= 1000 ppm TWA = 1900 mg/m^3 TWA
France OEL - TWA	= 1000 ppm VME = 1900 mg/m^3 VME
Germany - TRGS 900 - TWAs	= 500 ppm TWA = 960 mg/m^3 TWA
Greece OEL - TWA	= 1000 ppm TWA = 1900 mg/m^3 TWA
Hungary OEL - TWA	= 1900 mg/m^3 TWA
Ireland OEL - TWAs	= 1000 ppm TWA = 1900 mg/m^3 TWA
Latvia OEL - TWA	= 1000 mg/m^3 TWA
Lithuania OEL - TWA	= 1000 mg/m^3 IPRV = 500 ppm IPRV
Netherlands OEL - TWA	= 1000 mg/m^3 MAC = 500 ppm MAC
OSHA - Final PELS - TWAs:	= 1000 ppm TWA = 1900 mg/m^3 TWA
Poland OEL - TWA	= 1900 mg/m^3 NDS
Portugal OEL - TWA	= 1000 ppm TWA
Romania OEL - TWA	= 1000 ppm TWA = 1900 mg/m^3 TWA

Slovakia OEL - TWA	= 500 ppm TWA = 960 mg/m^3 TWA
Slovenia OEL - TWA	= 1000 ppm TWA = 1900 mg/m^3 TWA
Spain OEL - TWA	= 1000 ppm VLA-ED = 1910 mg/m^3 VLA-ED
Sweden OEL - TWAs	= 1000 mg/m^3 LLV = 500 ppm LLV

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/m^3 to < 1000ug/m^3)

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:

Physical State:	Syrupy liquid	**Color:**	Opaque
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

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)

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

Methyl-p-hydroxybenzoate
Mouse Oral LD50 >8 g/kg

Propylparaben
Mouse Oral LD 50 6332 mg/kg
Mouse Intraperitoneal LD 50 200 mg/kg

Sugar
Rat Oral LD 50 29700 mg/kg
Mouse Oral LD 50 14000 mg/kg

Glycerol
Rat Oral LD 50 12600 mg/kg

Sodium bicarbonate
Rat Oral LD50 4220 mg/kg
Mouse Oral LD50 3360 mg/kg
Rat Inhalation LC50 > 900 mg/m^3

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

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

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:	= 1000 lb final RQ = 454 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
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:	Present
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

Water, purified

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

Saccharin

CERCLA/SARA 313 Emission reporting	= 1.0 % de minimis concentration only persons who manufacture are subject, no supplier notification
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 100 lb final RQ = 45.4 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-321-0

Propylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-307-7

Methyl-p-hydroxybenzoate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-785-7

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

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End of Safety Data Sheet