MATERIAL SAFETY DATA SHEET

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
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Paromomycin Sulfate Capsules

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

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

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

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	%
Colloidal silicon dioxide	7631-86-9	231-545-4 EEC No. 418-260-2	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Paromomycin sulfate	1263-89-4	215-031-7	Not Listed	357 mg ***

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Hard gelatin capsules	MIXTURE	Not listed	Not Listed	*

Additional Information: * Proprietary
*** per tablet/capsule/lozenge/suppository
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA except stearates of toxic metals
Australia TWA	= 10 mg/m^3 TWA
Belgium OEL - TWA	= 10 mg/m^3 TWA
Ireland OEL - TWAs	= 10 mg/m^3 TWA except lead stearate
Lithuania OEL - TWA	= 3 mg/m^3 IPRV
Portugal OEL - TWA	= 10 mg/m^3 TWA does not include stearates of toxic metals
Spain OEL - TWA	= 10 mg/m^3 VLA-ED not including stearates of toxic metals
Sweden OEL - TWAs	= 5 mg/m^3 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 >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: Hard-gelatin Capsule **Color:** Yellow
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)

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m^3

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

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))

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.

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

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End of Safety Data Sheet