1. IDENTITY 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

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Spectinomycin Sterile Powder

Trade Name: TROBICIN; TOGAMYCIN
Chemical Family: Aminocyclitol
Intended Use: Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: White to off-white crystalline powder
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.

Additional Hazard Information:
Short Term: May cause eye irritation (based on components). Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

Known Clinical Effects: The most common adverse effects seen during clinical use of this drug include nausea, fever, vomiting, diarrhea and skin rash.

EU Indication of danger: Irritant

EU Hazard Symbols: Xi

EU Risk Phrases: R43 - May cause sensitization by skin contact.

Australian Hazard Classification (NOHSC):

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.
2. HAZARDS IDENTIFICATION

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>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spectinomycin Hydrochloride</td>
<td>21736-83-4</td>
<td>244-554-3</td>
<td>Xi;R43</td>
<td>100</td>
</tr>
</tbody>
</table>

Additional Information: 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. For information on potential delayed effects, see Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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: Formation of toxic gases is possible during heating or fire. May include oxides of carbon and products of nitrogen and chlorine.

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

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

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. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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.

Storage Conditions:
Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Spectinomycin Hydrochloride
Pfizer OEL TWA-8 Hr: 2000µg/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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

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.
Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Crystalline powder
Color: White to off-white
Odor: Odorless
Molecular Weight: Mixture
Molecular Formula: Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

SPECTINOMYCIN
11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of various forms of the active ingredients.

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

Spectinomycin Dihydrochloride Pentahydrate
Rat  Oral  LD 50  >5000 mg/kg
Rat  Sub-tenon injection (eye)  LD 50  2,020 mg/kg
Mouse Intraperitoneal  LD 50  2,350 mg/kg
Mouse Subcutaneous  LD 50  8,400 mg/kg

Spectinomycin Hydrochloride
Rat  Oral  LD 50  > 5000 mg/kg
Mouse Oral  LD 50  > 10,000 mg/kg
Rat  Intraperitoneal  LD 50  2020 mg/kg
Rat  Subcutaneous  LD 50  > 5000 mg/kg

Spectinomycin Sulfate Tetrahydrate
Rat  Oral  LD 50  >5000 mg/kg
Mouse Sub-tenon injection (eye)  LD 50  3577 mg/kg
Mouse Intravenous  LD 50  1022 mg/kg

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)

Spectinomycin Dihydrochloride Pentahydrate
Eye Irritation  Rabbit  Minimal
Skin Irritation  Rabbit  No effect

Spectinomycin Sulfate Tetrahydrate
Skin Irritation  Rabbit  No effect
Eye Irritation  Rabbit  Minimal

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

Spectinomycin Hydrochloride
90 Day(s)  Rat  Subcutaneous  1000 mg/kg/day  NOEL  None identified
2 Year(s)  Rat  Oral  400 mg/kg/day  NOAEL  None identified

Spectinomycin Sulfate Tetrahydrate
13 Week(s)  Rat  Oral  400 mg/kg/day  NOAEL  None identified
13 Week(s)  Rat  Oral  3000 mg/kg/day  LOAEL  None identified
90 Day(s)  Dog  Oral  50 mg/kg/day  NOAEL  None identified

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

Spectinomycin Hydrochloride
Fertility and Embryonic Development  Rabbit  Intramuscular  100 mg/kg/day  NOEL  No effects at maximum dose
Embryo / Fetal Development  Rat  Subcutaneous  2500 mg/kg/day  NOEL  Not Teratogenic
Embryo / Fetal Development  Mouse  Intraperitoneal  1600 mg/kg/day  NOAEL  No effects at maximum dose
11. TOXICOLOGICAL INFORMATION

**Spectinomycin Sulfate Tetrahydrate**
Reproductive & Fertility Rat Oral 400 mg/kg/day NOEL Maternal toxicity, Paternal toxicity, Fetotoxicity
Reproductive & Fertility Rat Oral 2000 mg/kg/day NOAEL Maternal Toxicity, Paternal toxicity, Fetotoxicity
Embryo / Fetal Development Rat Oral 1000 mg/kg/day NOAEL Maternal Toxicity
Embryo / Fetal Development Rat Oral 2000 mg/kg/day NOAEL Fetotoxicity

**Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**

- **Spectinomycin Dihydrochloride Pentahydrate**
  Bacterial Mutagenicity (Ames) *Salmonella* Negative
  
  *In Vivo* Micronucleus Rat Bone Marrow Negative

**Spectinomycin Sulfate Tetrahydrate**
Bacterial Mutagenicity (Ames) *Salmonella* Negative

*In Vitro* Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative
*In Vitro* Unscheduled DNA Synthesis Rat Hepatocyte Negative
*In Vivo* Micronucleus Mouse Bone Marrow Negative

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

12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided. The aquatic toxicity studies below were conducted with a chemically related material.

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

- **Spectinomycin Sulfate Tetrahydrate**
  *Selenastrum capricornutum* (Green Alga) OECD EC50 72 Hours 1.18 mg/L
  *Daphnia magna* (Water Flea) TAD EC50 48 Hours >1000 mg/L
  *Onchorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours >118 mg/L

**Aquatic Toxicity Comments:** A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

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

EU Symbol: Xi
EU Indication of danger: Irritant
EU Risk Phrases:
R43 - May cause sensitization by skin contact.

EU Safety Phrases:
S22 - Do not breathe dust.
S24 - Avoid contact with skin.
S37 - Wear suitable gloves.

OSHA Label:
WARNING
May cause allergic skin reaction.

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision B

Spectinomycin Hydrochloride
Australia (AICS):
Present
EU EINECS/ELINCS List
244-554-3

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3
R43 - May cause sensitization by skin contact.

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.

Prepared by:
Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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