



MATERIAL SAFETY DATA SHEET

Revision date: 11-Feb-2013

Version: 2.3

Page 1 of 7

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

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.
Hazardous Substance. Non-Dangerous Goods.

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.

MATERIAL SAFETY DATA SHEET

Material Name: Spectinomycin Sterile Powder
Revision date: 11-Feb-2013

Page 2 of 7
Version: 2.3

2. HAZARDS IDENTIFICATION

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Spectinomycin Hydrochloride	21736-83-4	244-554-3	Xi;R43	100

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.

MATERIAL SAFETY DATA SHEET

Material Name: Spectinomycin Sterile Powder
Revision date: 11-Feb-2013

Page 3 of 7
Version: 2.3

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

Analytical Method: Analytical method available for Spectinomycin. Contact Pfizer Inc for further information.

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 Formula:	Mixture
Molecular Weight:	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

MATERIAL SAFETY DATA SHEET

Material Name: Spectinomycin Sterile Powder
Revision date: 11-Feb-2013

Page 4 of 7
Version: 2.3

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

MATERIAL SAFETY DATA SHEET

Material Name: Spectinomycin Sterile Powder
Revision date: 11-Feb-2013

Page 5 of 7
Version: 2.3

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
Oncorhynchus 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.

MATERIAL SAFETY DATA SHEET

Material Name: Spectinomycin Sterile Powder
Revision date: 11-Feb-2013

Page 6 of 7
Version: 2.3

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

MATERIAL SAFETY DATA SHEET

Material Name: Spectinomycin Sterile Powder
Revision date: 11-Feb-2013

Page 7 of 7
Version: 2.3
