SAFETY DATA SHEET

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

Product Identifier

Material Name: Tobramycin in Sodium Chloride Injection (Hospira, Inc.)
Trade Name: Tobramycin Injection
Chemical Family: Aminoglycoside

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
Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

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
Skin Sensitization: Category 1
Reproductive Toxicity: Category 1A

Label Elements

Signal Word: Danger
Hazard Statements:
H317 - May cause an allergic skin reaction
H360D - May damage the unborn child

Precautionary Statements:
P202 - Do not handle until all safety precautions have been read and understood
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P272 - Contaminated work clothing must not be allowed out of the workplace
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P363 - Wash contaminated clothing before reuse
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Tobramycin sulfate</td>
<td>49842-07-1</td>
<td>256-499-2</td>
<td>Repr. 1A (H360D)</td>
<td>&lt;= 4</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Sens. 1 (H317)</td>
<td></td>
</tr>
<tr>
<td>Sulfuric acid</td>
<td>7664-93-9</td>
<td>231-639-5</td>
<td>Skin Corr. 1A (H314)</td>
<td>**</td>
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<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>Skin Corr. 1A (H314)</td>
<td>**</td>
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<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>Not Listed</td>
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<table>
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<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Water for injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:

* Proprietary
** to adjust pH

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 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.
SAFETY DATA SHEET

Material Name: Tobramycin in Sodium Chloride Injection (Hospira, Inc.)
Revision date: 19-Jun-2017

Version: 1.0
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5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

Fire / Explosion Hazards: Fine particles (such as dust and 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 the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.

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). 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.

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.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Tobramycin sulfate
Pfizer OEL TWA-8 Hr: 600µg/m³

Sulfuric acid
ACGIH Threshold Limit Value (TWA) 0.2 mg/m³
Australia STEL 3 mg/m³
Australia TWA 1 mg/m³
Austria OEL - MAKs 0.1 mg/m³
Belgium OEL - TWA 0.2 mg/m³
Bulgaria OEL - TWA 0.05 mg/m³
Cyprus OEL - TWA 0.05 mg/m³
Czech Republic OEL - TWA 1 mg/m³
Denmark OEL - TWA 0.05 mg/m³
Estonia OEL - TWA 1 mg/m³
Finland OEL - TWA 0.05 mg/m³
France OEL - TWA 0.05 mg/m³
Germany - TRGS 900 - TWAs 0.1 mg/m³
Germany (DFG) - MAK 0.1 mg/m³
Greece OEL - TWA 0.05 mg/m³
Hungary OEL - TWA 0.05 mg/m³
Ireland OEL - TWAs 0.05 ppm
Italy OEL - TWA 0.05 mg/m³
Japan - OELs - Ceilings 1 mg/m³
Latvia OEL - TWA 0.05 mg/m³
Lithuania OEL - TWA 0.05 mg/m³
Luxembourg OEL - TWA 0.05 mg/m³
Malta OEL - TWA 0.05 mg/m³
Netherlands OEL - TWA 0.05 mg/m³
OSHA - Final PELS - TWAs: 1 mg/m³
Poland OEL - TWA 0.05 mg/m³
Portugal OEL - TWA 0.05 mg/m³
Romania OEL - TWA 0.05 mg/m³
Slovakia OEL - TWA 0.1 mg/m³
Slovenia OEL - TWA 0.05 mg/m³
Spain OEL - TWA 0.05 mg/m³
Sweden OEL - TWAs 0.1 mg/m³
Switzerland OEL - TWAs 0.1 mg/m³
Vietnam OEL - TWAs 1 mg/m³

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
SAFETY DATA SHEET

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls

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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:
Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:
Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:
Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN116, ANSI Z87.1 or international equivalent.)

Respiratory protection:
Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Sterile solution
Odor: No data available.
Color: Clear, colorless
Molecular Formula: Mixture
Odor Threshold: No data available.
Molecular Weight: Mixture
Solvent Solubility: No data available
Water Solubility: No data available
pH: 3.0-6.5
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.

PZ03452
9. PHYSICAL AND CHEMICAL PROPERTIES

Partition Coefficient: (Method, pH, Endpoint, Value)
Water for injection
No data available
Sulfuric acid
No data available
SODIUM HYDROXIDE
No data available
Tobramycin sulfate
No data available
Sodium chloride
No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
  Autoignition Temperature (Solid) (°C): No data available
  Flammability (Solids): No data available
  Flash Point (Liquid) (°C): No data available
  Upper Explosive Limits (Liquid) (% by Vol.): No data available
  Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

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 dust and 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.
Short Term: May cause eye and skin irritation (based on components).
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on kidneys.
Known Clinical Effects: May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Adverse effects most commonly reported in clinical use include effects on hearing, nausea, vomiting, and vertigo (vestibular ototoxicity), nervous system/brain toxicity (neurotoxicity), and kidney toxicity (nephrotoxicity). May cause adverse effects on the developing fetus. Serious allergic reactions, including anaphylaxis, have been reported.

Acute Toxicity: (Species, Route, End Point, Dose)
11. TOXICOLOGICAL INFORMATION

Sulfuric acid
Rat  Oral  LD50  2140 mg/kg

Tobramycin sulfate
Rat  Oral  LD50  > 7500 mg/kg
Rat  Para-periosteal  LD50  133 mg/kg

Sodium chloride
Rat  Oral  LD50  3000 mg/kg
Mouse  Oral  LD50  4000 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)

Sulfuric acid
Eye Irritation  Rabbit  Severe

Tobramycin sulfate
Eye Irritation  Rabbit  Slight
Skin Irritation  Rabbit  Slight

Sodium chloride
Eye Irritation  Rabbit  Moderate
Skin Irritation  Rabbit  Mild

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Tobramycin sulfate
Reproductive & Fertility  Rat  Subcutaneous  100 mg/kg/day  NOAEL  No effects at maximum dose
Embryo / Fetal Development  Rat  Subcutaneous  100 mg/kg/day  NOAEL  No effects at maximum dose
Embryo / Fetal Development  Rabbit  Subcutaneous  20 mg/kg/day  LOAEL  Maternal Toxicity, Fetal mortality

Carcinogen Status: None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

Sulfuric acid
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: No data available

Persistence and Degradability: No data available
Bio-accumulative Potential: No data available
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

Tobramycin sulfate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: developmental toxicity 7/1/1990
- Australia (AICS): Present
- EU EINECS/ELINCS List: 256-499-2

Sulfuric acid
- CERCLA/SARA 313 Emission reporting: 1.0 %
- CERCLA/SARA Hazardous Substances and their Reportable Quantities:
  - 1000 lb
  - 454 kg
- CERCLA/SARA - Section 302 Extremely Hazardous TPQs: 1000 lb
- CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
15. REGULATORY INFORMATION

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<th>Australia (AICS):</th>
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<td>Schedule 6</td>
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Water for injection

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<td>Australia (AICS):</td>
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<td>REACH - Annex IV - Exemptions from the obligations of Register:</td>
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SODIUM HYDROXIDE

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<tr>
<td>CERCLA/SARA Hazardous Substances</td>
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<td>and their Reportable Quantities:</td>
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Sodium chloride

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<td>EU EINECS/ELINCS List</td>
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16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction
Reproductive toxicity-Cat.1A; H360D - May damage the unborn child

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

Reasons for Revision: New data sheet.

Revision date: 19-Jun-2017


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