



# MATERIAL SAFETY DATA SHEET

Revision date: 03-Dec-2007

Version: 1.2

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

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## Material Name: Tobramycin Sulfate Solution, For Injection, IM/IV (Preservative Free)

Trade Name: Tobramycin Injection  
Chemical Family: Aminoglycoside  
Intended Use: Pharmaceutical product used as antibiotic agent

## 2. HAZARDS IDENTIFICATION

Appearance: Colorless, sterile solution  
Signal Word: DANGER

Statement of Hazard: May cause allergic skin reaction.  
May damage the unborn child.

Additional Hazard Information:  
Short Term: May cause 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), kidney toxicity (nephrotoxicity). May cause adverse effects on the developing fetus. Serious allergic reactions, including anaphylaxis, have been reported.

EU Indication of danger: Irritant  
Toxic to reproduction: Category 1

### EU Hazard Symbols:



EU Risk Phrases:  
R43 - May cause sensitization by skin contact.  
R61 - May cause harm to the unborn child.

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

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**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	%
Tobramycin sulfate	49842-07-1	256-499-2	Repr. Cat.1;R61 Xi;R43	0-4
Sulfuric acid	7664-93-9	231-639-5	C;R35	**

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Disodium EDTA (dihydrate)	6381-92-6	Not listed	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	*

### Additional Information:

\* Proprietary  
\*\* to adjust pH  
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:** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

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

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

### 6. ACCIDENTAL RELEASE MEASURES

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Cleaning / Collecting:</b>	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.
<b>Measures for Environmental Protections:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills:</b>	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

<b>General Handling:</b>	Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8).
<b>Storage Conditions:</b>	Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

#### Sulfuric acid

ACGIH Threshold Limit Value (TWA)	= 0.2 mg/m <sup>3</sup> TWA
Australia STEL	= 3 mg/m <sup>3</sup> STEL
Australia TWA	= 1 mg/m <sup>3</sup> TWA
Austria OEL - MAKs	= 1 mg/m <sup>3</sup> MAK
Belgium OEL - TWA	= 1 mg/m <sup>3</sup> TWA
Bulgaria OEL - TWA	= 1.0 mg/m <sup>3</sup> TWA
Czech Republic OEL - TWA	= 1 mg/m <sup>3</sup> TWA
Denmark OEL - TWA	= 1 mg/m <sup>3</sup> TWA
Estonia OEL - TWA	= 1 mg/m <sup>3</sup> TWA
Finland OEL - TWA	= 0.2 mg/m <sup>3</sup> TWA
France OEL - TWA	= 1 mg/m <sup>3</sup> VME
Greece OEL - TWA	= 1 mg/m <sup>3</sup> TWA
Hungary OEL - TWA	= 1 mg/m <sup>3</sup> TWA
Ireland OEL - TWAs	= 1 mg/m <sup>3</sup> TWA
Latvia OEL - TWA	= 1 mg/m <sup>3</sup> TWA
Lithuania OEL - TWA	= 1 mg/m <sup>3</sup> IPRV
Netherlands OEL - TWA	= 1 mg/m <sup>3</sup> MAC
OSHA - Final PELS - TWAs:	= 1 mg/m <sup>3</sup> TWA
Poland OEL - TWA	= 1 mg/m <sup>3</sup> NDS
Portugal OEL - TWA	= 1 mg/m <sup>3</sup> TWA
Romania OEL - TWA	= 0.50 mg/m <sup>3</sup> TWA
Slovakia OEL - TWA	= 0.1 mg/m <sup>3</sup> TWA
Slovenia OEL - TWA	= 0.1 mg/m <sup>3</sup> TWA
Spain OEL - TWA	= 1 mg/m <sup>3</sup> VLA-ED
Sweden OEL - TWAs	= 1 mg/m <sup>3</sup> LLV

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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.

### Tobramycin sulfate

**Pfizer Occupational Exposure** OEB2 (control exposure to the range of >100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>)  
**Band (OEB):**

#### 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:

<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

## 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Sterile solution	<b>Color:</b>	Colorless
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

## 10. STABILITY AND REACTIVITY

<b>Stability:</b>	Stable under normal conditions of use.
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	Strong acids and oxidizers
<b>Polymerization:</b>	Will not occur

## 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)

##### Tobramycin sulfate

Rat Oral LD50 > 7500 mg/kg  
Rat Intravenous LD50 133 mg/kg

##### Sulfuric acid

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Rat Oral LD50 2140 mg/kg

### Irritation / Sensitization: (Study Type, Species, Severity)

#### **Tobramycin sulfate**

Eye Irritation Rabbit Slight  
Skin Irritation Rabbit Slight

#### **Sulfuric acid**

Eye Irritation Rabbit Severe

### 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  
**NTP:** Known Carcinogen  
**OSHA:** Present

## **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.

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### 15. REGULATORY INFORMATION

EU Symbol:

T

EU Indication of danger:

Irritant

Toxic to reproduction: Category 1

EU Risk Phrases:

R43 - May cause sensitization by skin contact.

R61 - May cause harm to the unborn child.

EU Safety Phrases:

S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:

DANGER

May cause allergic skin reaction.

May damage the unborn child.

### Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A

Class D, Division 2, Subdivision B



Tobramycin sulfate

California Proposition 65

developmental toxicity, initial date 7/1/90

Australia (AICS):

Present

EU EINECS/ELINCS List

256-499-2

Disodium EDTA (dihydrate)

Australia (AICS):

Present

Sulfuric acid

CERCLA/SARA 313 Emission reporting

= 1.0 % de minimis concentration acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size

CERCLA/SARA Hazardous Substances and their Reportable Quantities:

= 1000 lb final RQ

CERCLA/SARA - Section 302 Extremely Hazardous TPQs

= 454 kg final RQ

= 1000 lb TPQ

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CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 1000 lb EPCRA RQ
California Proposition 65	carcinogen, initial date 3/14/03
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	231-639-5

### Water for injection

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

## 16. OTHER INFORMATION

### Text of R phrases mentioned in Section 3

R35 - Causes severe burns.  
R43 - May cause sensitization by skin contact.  
R61 - May cause harm to the unborn child.

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

**Prepared by:** Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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**End of Safety Data Sheet**