



# MATERIAL SAFETY DATA SHEET

Revision date: 13-Sep-2011

Version: 1.3

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

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### Material Name: Tobramycin Sulfate Injection

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

### EU Hazard Symbols:



### EU Risk Phrases:

R43 - May cause sensitization by skin contact.  
R61 - May cause harm to the unborn child.  
Hazardous Substance. Non-Dangerous Goods.

### Australian Hazard Classification (NOHSC):

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### 2. HAZARDS IDENTIFICATION

**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	EU 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	**
Phenol	108-95-2	203-632-7	C;R34 T;R24/25	0-1
Sodium metabisulfite USP	7681-57-4	231-673-0	R31 Xi; R41 Xn; R22	0-1

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

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### 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.
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 the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.
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:	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.
Storage Conditions:	Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Tobramycin sulfate	
Pfizer OEL TWA-8 Hr:	600µg/m <sup>3</sup>
Sulfuric acid	
ACGIH Threshold Limit Value (TWA)	0.2 mg/m <sup>3</sup>
Australia STEL	3 mg/m <sup>3</sup>
Australia TWA	1 mg/m <sup>3</sup>
Austria OEL - MAKs	1 mg/m <sup>3</sup>
Belgium OEL - TWA	1 mg/m <sup>3</sup>
Bulgaria OEL - TWA	1.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	1 mg/m <sup>3</sup>
Denmark OEL - TWA	1 mg/m <sup>3</sup>
Estonia OEL - TWA	1 mg/m <sup>3</sup>
Finland OEL - TWA	0.2 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

France OEL - TWA	1 mg/m <sup>3</sup>
Germany (DFG) - MAK	0.1 mg/m <sup>3</sup> inhalable fraction
Greece OEL - TWA	1 mg/m <sup>3</sup>
Hungary OEL - TWA	1 mg/m <sup>3</sup>
Ireland OEL - TWAs	1 mg/m <sup>3</sup>
Japan - OELs - Ceilings	1 mg/m <sup>3</sup>
Latvia OEL - TWA	1 mg/m <sup>3</sup>
Lithuania OEL - TWA	1 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	1 mg/m <sup>3</sup>
Poland OEL - TWA	1 mg/m <sup>3</sup>
Portugal OEL - TWA	0.2 mg/m <sup>3</sup>
Romania OEL - TWA	0.50 mg/m <sup>3</sup>
Slovakia OEL - TWA	0.1 mg/m <sup>3</sup>
Slovenia OEL - TWA	0.1 mg/m <sup>3</sup>
Spain OEL - TWA	1 mg/m <sup>3</sup>
Sweden OEL - TWAs	1 mg/m <sup>3</sup>

#### Phenol

ACGIH Threshold Limit Value (TWA)	5 ppm
ACGIH - Biological Exposure Limit:	250 mg/g creatinine
ACGIH - Skin Absorption Designation	Skin - potential significant contribution to overall exposure by the cutaneous route
Australia TWA	1 ppm
	4 mg/m <sup>3</sup>
Austria OEL - MAKs	2 ppm
	7.8 mg/m <sup>3</sup>
Belgium OEL - TWA	2 ppm
	7.8 mg/m <sup>3</sup>
Bulgaria OEL - TWA	7.8 mg/m <sup>3</sup>
Bulgaria - Biological Exposure Limit:	200 mg/L
Cyprus OEL - TWA	2 ppm
	7.8 mg/m <sup>3</sup>
Czech Republic OEL - TWA	7.5 mg/m <sup>3</sup>
Denmark OEL - TWA	1 ppm
	4 mg/m <sup>3</sup>
Estonia OEL - TWA	2 ppm
	7.8 mg/m <sup>3</sup>
Finland OEL - TWA	2 ppm
	8 mg/m <sup>3</sup>
Finland - Biological Exposure Limit:	1.3 mmol/L
France OEL - TWA	2 ppm
	7.8 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	2 ppm
	8 mg/m <sup>3</sup>
Germany - Biological Exposure Limit:	300 mg/L
Greece OEL - TWA	5 ppm
	19 mg/m <sup>3</sup>
Hungary OEL - TWA	7.8 mg/m <sup>3</sup>
Ireland OEL - TWAs	2 ppm
	8 mg/m <sup>3</sup>
Italy OEL - TWA	2 ppm
	7.8 mg/m <sup>3</sup>

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## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Latvia OEL - TWA	2 ppm 7.8 mg/m <sup>3</sup>
Lithuania OEL - TWA	2 ppm 7.8 mg/m <sup>3</sup>
Luxembourg OEL - TWA	2 ppm 7.8 mg/m <sup>3</sup>
Malta OEL - TWA	2 ppm 7.8 mg/m <sup>3</sup>
Netherlands OEL - TWA	8 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	5 ppm 19 mg/m <sup>3</sup>
OSHA - Final PELs - Skin Notations:	prevent or reduce skin absorption
Poland OEL - TWA	7.8 mg/m <sup>3</sup>
Portugal OEL - TWA	5 ppm
Romania OEL - TWA	2 ppm 7.8 mg/m <sup>3</sup>
Romania - Biological Exposure Limit:	50 mg/L
Slovakia OEL - TWA	2 ppm 7.8 mg/m <sup>3</sup>
Slovak Republic - Biological Exposure Limit:	200 mg/L
Slovenia OEL - TWA	2 ppm 7.8 mg/m <sup>3</sup>
Spain OEL - TWA	2 ppm 8 mg/m <sup>3</sup>
Spain - Biological Exposure Limit:	250 mg/g Creatinine
Sweden OEL - TWAs	1 ppm 4 mg/m <sup>3</sup>

### Sodium metabisulfite USP

ACGIH Threshold Limit Value (TWA)	5 mg/m <sup>3</sup>
Australia TWA	5 mg/m <sup>3</sup>
Belgium OEL - TWA	5 mg/m <sup>3</sup>
Denmark OEL - TWA	5 mg/m <sup>3</sup>
France OEL - TWA	5 mg/m <sup>3</sup>
Greece OEL - TWA	5 mg/m <sup>3</sup>
Ireland OEL - TWAs	5 mg/m <sup>3</sup>
Portugal OEL - TWA	5 mg/m <sup>3</sup>
Spain OEL - TWA	5 mg/m <sup>3</sup>

<b>Engineering Controls:</b>	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.
<b>Environmental Exposure Controls:</b>	Refer to specific Member State legislation for requirements under Community environmental legislation.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<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.

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Respiratory protection:** 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
<b>pH:</b>	3.0-6.0		
<b>Polymerization:</b>	Will not occur		

### 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:** Strong acids and oxidizers

### 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 Para-periosteal LD50 133 mg/kg

##### **Sulfuric acid**

Rat Oral LD50 2140 mg/kg

##### **Phenol**

Rat Oral LD50 317 mg/kg  
Rat Dermal LD50 669 mg/kg  
Rat Inhalation LC50 316 mg/m<sup>3</sup>

**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)

##### **Tobramycin sulfate**

Eye Irritation Rabbit Slight  
Skin Irritation Rabbit Slight

##### **Sulfuric acid**

Eye Irritation Rabbit Severe

##### **Phenol**

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## 11. TOXICOLOGICAL INFORMATION

Eye Irritation	Rabbit	Severe
Skin 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

<b>IARC:</b>	Group 1 (Carcinogenic to Humans)
<b>OSHA:</b>	Listed

## Sodium metabisulfite USP

**IARC:** Group 3 (Not Classifiable)

## Phenol

**IARC:** Group 3 (Not Classifiable)

## 12. ECOLOGICAL INFORMATION

### Environmental Overview:

Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

### 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.

## Phenol

RCRA - U Series Wastes	Listed
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## 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.

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### 15. REGULATORY INFORMATION

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

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



(Bad file name or number)

#### Tobramycin sulfate

California Proposition 65	developmental toxicity initial date 7/1/90
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
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	454 kg
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	1000 lb
Inventory - United States TSCA - Sect. 8(b)	1000 lb
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 6
	231-639-5

#### Water for injection

Inventory - United States TSCA - Sect. 8(b)	Present
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### 15. REGULATORY INFORMATION

Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2
Disodium EDTA (dihydrate)	
Australia (AICS):	Present
Phenol	
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	500 lb 10000 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	1000 lb
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 4 Schedule 5 Schedule 6
EU EINECS/ELINCS List	203-632-7
Sodium metabisulfite USP	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
EU EINECS/ELINCS List	231-673-0

### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.  
R31 - Contact with acids liberates toxic gas.  
R34 - Causes burns.  
R41 - Risk of serious damage to eyes.  
R43 - May cause sensitization by skin contact.  
R61 - May cause harm to the unborn child.  
R24/25 - Toxic in contact with skin and if swallowed.

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

**Reasons for Revision:** Updated Section 8 - Exposure Controls / Personal Protection.

**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.

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End of Safety Data Sheet