

# Tobramycin for Injection, USP

## Safety Data Sheet

### SECTION 1: Identification

#### 1.1. Identification

Product name : Tobramycin for Injection, USP  
Other means of identification : Pharmacy Bulk Package Vials, carton of 6, NDC 55150-470-06

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

#### 1.3. Details of the supplier of the safety data sheet

Eugia US LLC  
279 Princeton Hightstown Road  
East Windsor, NJ 08520

#### 1.4. Emergency telephone number

Emergency number : 1-888-238-7880

### SECTION 2: Hazard(s) identification

#### 2.1. Classification of the substance or mixture

##### GHS US classification

Skin Corr. 1 H314  
Eye Dam. 1 H318  
Resp. Sens. 1 H334  
Skin Sens. 1 H317  
Repr. 1A H360

Full text of hazard classes and H-statements : see section 16

#### 2.2. Label elements

##### GHS US labeling

Hazard pictograms (GHS US) :



GHS05

GHS08

Signal word (GHS US) :

Danger

Hazard statements (GHS US) :

H314 - Causes severe skin burns and eye damage  
H317 - May cause an allergic skin reaction  
H318 - Causes serious eye damage  
H334 - May cause an allergy or asthma symptoms or breathing difficulties if inhaled  
H360 - May damage fertility or the unborn child

Precautionary statements (GHS US) :

P201 - Obtain special instructions before use.  
P202 - Do not handle until all safety precautions have been read and understood.  
P260 - Do not breathe dust/fume/gas/mist/vapors/spray.  
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.  
P264 - Wash hands, forearms and face thoroughly after handling.  
P272 - Contaminated work clothing must not be allowed out of the workplace.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection.  
P284 - [In case of inadequate ventilation] wear respiratory protection.  
P301+P330+P331 - If swallowed: rinse mouth. Do NOT induce vomiting.  
P302+P352 - If on skin: Wash with plenty of water.  
P303+P361+P353 - If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.  
P304+P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing.  
P304+P341 - If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.  
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P308+P313 - If exposed or concerned: Get medical advice/attention.  
P310 - Immediately call a poison center or doctor.  
P321 - Specific treatment (see supplemental first aid instruction on this label).  
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.  
P342+P311 - If experiencing respiratory symptoms: Call a poison center or doctor.

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P363 - Wash contaminated clothing before reuse.  
P405 - Store locked up.  
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

### 2.3. Other hazards

No additional information available

### 2.4. Unknown acute toxicity (GHS US)

Not applicable

## SECTION 3: Composition/Information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	GHS US classification
Tobramycin	(CAS-No.) 32986-56-4	4	Not classified
Sulfuric acid	(CAS-No.) 7664-93-9	2.09	Skin Corr. 1A, H314
Sodium hydroxide	(CAS-No.) 1310-73-2	< 1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318

Full text of hazard classes and H-statements : see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after inhalation : If not breathing, give artificial respiration.  
First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.  
First-aid measures after eye contact : In case of dust contact with eyes, rinse immediately with plenty of water.  
First-aid measures after ingestion : Go into open air and ventilate suspected area.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation : May cause an allergy or asthma symptoms or breathing difficulties if inhaled.  
Symptoms/effects after skin contact : Causes severe skin burns. May cause an allergic skin reaction.  
Symptoms/effects after eye contact : Causes serious eye damage.  
Symptoms/effects after ingestion : May cause an allergy or asthma symptoms or breathing difficulties if inhaled.

### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.  
Unsuitable extinguishing media : None.

### 5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

### 5.3. Advice for firefighters

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

#### 6.1.1. For non-emergency personnel

No additional information available

#### 6.1.2. For emergency responders

### 6.2. Environmental precautions

Prevent entry to sewers and public waters.

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### 6.3. Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.  
Methods for cleaning up : Recycle product or dispose safely.

### 6.4. Reference to other sections

No additional information available

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Do not eat, drink or smoke when using this product.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at 20° to 25°C (68° to 77°F).

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Tobramycin (32986-56-4)		
Not applicable		
Sulfuric acid (7664-93-9)		
ACGIH	ACGIH OEL TWA	0.2 mg/m <sup>3</sup> (thoracic particulate matter)
OSHA	OSHA PEL (TWA) [1]	1 mg/m <sup>3</sup>
IDLH	IDLH	15 mg/m <sup>3</sup>
NIOSH	NIOSH REL (TWA)	1 mg/m <sup>3</sup>
Sodium hydroxide (1310-73-2)		
ACGIH	ACGIH OEL Ceiling	2 mg/m <sup>3</sup>
OSHA	OSHA PEL (TWA) [1]	2 mg/m <sup>3</sup>
IDLH	IDLH	10 mg/m <sup>3</sup>
NIOSH	NIOSH REL (Ceiling)	2 mg/m <sup>3</sup>

### 8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.  
Hand protection : Use neoprene or rubber gloves.  
Eye protection : In case of dust production: protective goggles.  
Skin and body protection : Wear suitable working clothes.  
Respiratory protection : Wear NIOSH approved respirator when handling.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state : Solid  
Appearance : Lyophilized powder  
Color : White to off-white  
Odor : Odorless  
Odor threshold : No data available  
pH : No data available  
Melting point : No data available  
Freezing point : No data available  
Boiling point : No data available  
Flash point : No data available  
Relative evaporation rate (butyl acetate=1) : No data available  
Flammability : No data available  
Vapor pressure : No data available  
Relative vapor density at 20°C : No data available

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Relative density	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

The product is stable at normal handling and storage conditions.

### 10.3. Possibility of hazardous reactions

Will not occur.

### 10.4. Conditions to avoid

Air contact.

### 10.5. Incompatible materials

None known.

### 10.6. Hazardous decomposition products

None known.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Not classified

<b>Tobramycin (32986-56-4)</b>	
LD50 oral rat	> 7500 mg/kg
<b>Sulfuric acid (7664-93-9)</b>	
LD50 oral rat	2140 mg/kg
LC50 Inhalation - Rat	85 – 103 mg/m <sup>3</sup> (Exposure time: 1 h)
ATE US (oral)	2140 mg/kg body weight
ATE US (vapors)	0.085 mg/l/4h
ATE US (dust, mist)	0.085 mg/l/4h
<b>Sodium hydroxide (1310-73-2)</b>	
LD50 oral rat	140 – 340 mg/kg
LD50 dermal rabbit	1350 mg/kg
ATE US (dermal)	1350 mg/kg

Skin corrosion/irritation	: Causes severe skin burns.
Serious eye damage/irritation	: Causes serious eye damage.
Respiratory or skin sensitization	: May cause an allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

<b>Sulfuric acid (7664-93-9)</b>	
IARC group	1 - Carcinogenic to humans
In OSHA Hazard Communication Carcinogen list	Yes

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Reproductive toxicity	: May damage fertility or the unborn child.
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

### SECTION 12: Ecological information

#### 12.1. Toxicity

<b>Sulfuric acid (7664-93-9)</b>	
LC50 - Fish [1]	> 500 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [static])
<b>Sodium hydroxide (1310-73-2)</b>	
LC50 - Fish [1]	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

#### 12.2. Persistence and degradability

No additional information available

#### 12.3. Bioaccumulative potential

<b>Sulfuric acid (7664-93-9)</b>	
BCF - Fish [1]	(no bioaccumulation)

#### 12.4. Mobility in soil

No additional information available

#### 12.5. Other adverse effects

No additional information available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

### SECTION 14: Transport information

#### Department of Transportation (DOT)

In accordance with DOT

Not applicable

#### International Air Transport Association (IATA)

In accordance with IATA

Not applicable

### SECTION 15: Regulatory information

#### 15.1. US Federal regulations

<b>Sulfuric acid (7664-93-9)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory Listed on the United States SARA Section 302 Subject to reporting requirements of United States SARA Section 313	
CERCLA RQ	1000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	1000 lb
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

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### Sodium hydroxide (1310-73-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

CERCLA RQ

1000 lb

### 15.2. US State regulations

#### Sulfuric acid (7664-93-9)

U.S. - Massachusetts - Right To Know List

U.S. - Minnesota - Hazardous Substance List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

#### Sodium hydroxide (1310-73-2)

U.S. - Massachusetts - Right To Know List

U.S. - Minnesota - Hazardous Substance List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

## SECTION 16: Other information

Full text of H-phrases:

Eye Dam. 1	Serious eye damage/eye irritation Category 1
Met. Corr. 1	Corrosive to metals Category 1
Repr. 1A	Reproductive toxicity Category 1A
Resp. Sens. 1	Respiratory sensitization, Category 1
Skin Corr. 1	Skin corrosion/irritation Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Sens. 1	Skin sensitization, Category 1
H290	May be corrosive to metals
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H334	May cause an allergy or asthma symptoms or breathing difficulties if inhaled
H360	May damage fertility or the unborn child

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*