

**TOBRAMYCINI SULFAS**

**SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**

**1.1 Product identifier**

Product name: Tobramycin sulfate  
Tobramycini sulfas  
Tobramycinesulfaat  
Tobramycine (sulfate de)  
Tobramycinsulfat

N° CAS: 79645-27-5

N° EC: 616-717-2

**1.2 Relevant identified uses of the substance/mixture and uses advised against**

Identified uses: Active Pharmaceutical Ingredient.

**1.3 Details of the supplier of the safety data sheet**

Company: Magis-Pharma NV  
Neerlandweg 24  
2610 Wilrijk  
Belgium

Telephone: (+32) (0)3 457 11 76

Email: info@magis-pharma.be

Web page: www.magis-pharma.be

**1.4 Emergency telephone number**

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

**SECTION 2: HAZARDS IDENTIFICATION**

**2.1 Classification of the substance/mixture**

**Classification according to (EC) n° 1272/2008**

Acute Tox. 4	H312
Acute Tox. 4	H332
Repr. 1B	H360

**2.2 Label elements**

**Labelling according to (EC) n° 1272/2008**

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

## TOBRAMYCINI SULFAS

H312	Harmful in contact with skin.
H332	Harmful if inhaled.
H360	May damage fertility or the unborn child.
Precautionary statements:	
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P203	Obtain, read and follow all safety instructions before use.
P261	Avoid breathing dust/fume/gas/mist/vapors/spray.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P281	Use personal protective equipment as required.
P302+P352	IF ON SKIN: wash with plenty of water.
P304+P312	IF INHALED: Call a POISON CENTER/doctor/... if you feel unwell.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P312	Call a POISON CENTER/doctor/... if you feel unwell.
P317	Get emergency medical help.
P318	If exposed or concerned, get medical advice.
P321	Specific treatment (see section 4 on this label).
P322	Specific measures (see ... on this label).
P362+P364	Take off contaminated clothing and wash it before reuse.
P363	Wash contaminated clothing before reuse
P405	Store in a closed container.
P501	Dispose of contents/container to local/regional/national/international regulations.

Additional applicable label elements:



### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Tobramycin sulfate
IUPAC name:	4-amino-2-[4,6-diamino-3-[3-amino-6-(aminomethyl)-5-hydroxyoxan-2-yl]oxy-2-hydroxycyclohexyl]oxy-6-(hydroxymethyl)oxane-3,5-diol;sulfuric acid
Synonyms:	Trobamycinsulfate Sulfuric acid; trobamycin

## TOBRAMYCINI SULFAS

N° CAS:	(2S,3R,4S,5S,6R)-4-amino-2-[(1S,2S,3R,4S,6R)-4,6-diamino-3-[(2R,3R,5S,6R)-3-amino-6-(aminomethyl)-5-hydroxyoxan-2-yl]oxy-2-hydroxycyclohexyl]oxy-6-(hydroxymethyl)oxane-3,5-diol,sulfuric acid
N° EC:	79645-27-5
Molecular Formula:	616-717-2
Content:	$C_{18}H_{39}N_5O_{13}S$
	Tobramycin sulfate has a potency of NLT 634 µg/mg and NMT 739 µg/mg of tobramycin ( $C_{18}H_{37}N_5O_9$ ).

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

After inhalation:	Remove from source of exposure. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention. Provide symptomatic/supportive care as necessary.
After skin contact:	Remove from source of exposure. In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical Attention. Provide symptomatic/supportive care as necessary.  Serious skin contact: Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek medical attention.
After eye contact:	Check for and remove from source of exposure. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
After ingestion:	Remove from source of exposure. Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear. Provide symptomatic/supportive care as necessary.

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

Not available.

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

Not available.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media:	<b>Small fire:</b> Use dry chemical powder. <b>Large fire:</b> Use water spray, fog or foam.
-------------------------------	---

**TOBRAMYCINI SULFAS**

Unsuitable extinguishing media:

Do not use water jet.

**5.2 Special hazards arising from the substance/mixture**

Flammability of the Product: May be combustible at high temperature.

Fire Hazards in Presence of Various Substances: Slightly flammable to flammable in presence of open flames and sparks, of heat.

**5.3 Advice for firefighters**

Surrounding fires:

Not available.

Protection against fire:

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Hazardous combustion products:

These products are carbon oxides (CO, CO<sub>2</sub>), nitrogen oxides (NO, NO<sub>2</sub>...).

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

**6.1 Personal precautions, protective equipment and emergency procedures**

**For non-emergency personnel**

General Information: Use proper personal protective equipment as listed in 8.

**For emergency responders**

General Information: Use proper personal protective equipment as listed in 8.

**6.2 Environmental precautions**

Not available.

**6.3 Methods and material for containment and cleaning up**

**Small spill:** Use appropriate tools to put the spilled material in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose according to local and regional authority requirements.

**Large spill:** Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

**6.4 Reference to other sections**

Not available.

**SECTION 7: HANDLING AND STORAGE**

**7.1 Precautions for safe handling**

Precautions for safe handling:

Keep away from heat. Keep away from sources of ignition. Do not ingest. Do not breathe dust. If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes. Keep away from incompatibles such as oxidizing agents, acids.

Personal protection:

Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment.

## TOBRAMYCINI SULFAS

Technical protective measures:

Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material.

Handling:

Not available.

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

Storage:

Preserve in tight containers.

Conditions for safe storage, including any incompatibilities:

Not available.

Storage – away from:

Keep away from heat. Keep away from sources of ignition. Keep away from incompatibles such as oxidizing agents, acids.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Not available.

### 8.2 Exposure controls

#### Appropriate engineering control

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit. Facilities storing or utilizing this material should be equipped with an eyewash and a safety shower facility.

#### Individual protection measures

Eye/face protection:

Wear chemical safety goggles. In case of large spill: Splash goggles.

Skin protection:

Lab coat. In case of large spill: Full suit. Boots. Suggested protective clothing might not be sufficient; consult a specialist before handling this product.

Hand protection:

Wear compatible chemical-resistant protective gloves. In case of large spill: Gloves.

Respiratory protection:

Use respirators and components tested and approved under appropriate government standards such as NIOSH (US). In case of large spill: Dust respirator. A self-contained breathing apparatus should be used to avoid inhalation of the product.

Thermal hazards:

Not determined.

#### Environmental exposure control

Not available.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance:

White or almost white powder.

Odour:

Odourless.

## TOBRAMYCINI SULFAS

Odour threshold:	Not available.
pH:	6.0 – 8.0
Melting/freezing point:	Not available.
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Not available.
Solubility in water:	Soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

### 9.2 Other information

Molecular weight: 1425.42g/mole

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Not available.

### 10.2 Chemical stability

The product is stable.

### 10.3 Possibility of hazardous reactions

Not available.

### 10.4 Conditions to avoid

Not available.

### 10.5 Incompatible materials

Reactive with oxidizing agents, acids.

**TOBRAMYCINI SULFAS**

**10.6 Hazardous decomposition products**

Will not occur.

**SECTION 11: TOXICOLOGICAL INFORMATION**

**11.1 Information on toxicological effects**

Acute toxicity:	LD <sub>50</sub> (Oral, Mouse): 10500 mg/kg LD <sub>50</sub> (subcutaneous, Rat): 1680 mg/kg LC <sub>50</sub> (Inhalation, Rat): 6800 mg/m <sup>3</sup>
Skin corrosion/irritation:	Hazardous in case of skin contact (irritant).
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Chronic effects on humans: May cause damage to the following organs: kidneys, ears.

**11.2 Additional information on potential adverse human health effects and symptoms**

Eye contact:	Not available.
Skin contact:	Hazardous in case of skin contact (irritant).
Inhalation:	Hazardous in case of inhalation (lung irritant).
Ingestion:	Hazardous in case of ingestion.
Aspiration:	Not available.

**SECTION 12: ECOLOGICAL INFORMATION**

**12.1 Toxicity**

Not available.

**12.2 Persistence and degradability**

Products of Biodegradation: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

**12.3 Bioaccumulative potential**

Not available.

## TOBRAMYCINI SULFAS

### 12.4 Mobility in soil

Not available.

### 12.5 Results of PBT and vPvB assessment

Not available.

### 12.6 Other adverse effects

Not available.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

Waste disposal: Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all federal, state, and local environmental regulations.

## SECTION 14: TRANSPORT INFORMATION

### Transport information according to ADR/RID/IMDG/ICAO/IATA

#### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea), Not classified.  
IATA/ICAO (Air) :

#### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), Not classified.  
IATA/ICAO (Air) :

#### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), Not classified.  
IATA/ICAO (Air) :

#### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea), Not classified.  
IATA/ICAO (Air) :

#### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), Not classified.  
IATA/ICAO (Air) :

#### 14.6 Special precautions for user

Not applicable.

#### 14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

#### 14.8 Additional transport information

DOT Classification: Not a DOT controlled material (United States).

## SECTION 15: REGULATORY INFORMATION

**TOBRAMYCINI SULFAS**

**15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture**

Hazard symbol:



Danger

Risk phrases:

R60 May impair fertility.

R61 May cause harm to the unborn child.

R20/21/22 Harmful by inhalation, in contact with skin.

Safety phrases:

S1 Keep locked up.

S22 Do not breathe dust.

S28 After contact with skin, wash immediately with plenty of water.

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

S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

S51 Use only in well-ventilated areas.

S53 Avoid exposure - obtain special instructions before use.

S63 In case of accident by inhalation: remove casualty to fresh air and keep at rest.

**15.2 Chemical safety assessment**

Not available.

**SECTION 16: OTHER INFORMATION**

**16.1 Changes since the previous version**

Not applicable.

**16.2 Abbreviations and acronyms used**

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

**16.3 Key literature references/sources for data**

**TOBRAMYCINI SULFAS**

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

**16.4 Method of classification in case of mixture**

Not applicable.

**16.5 Relevant Hazard statements and/or precautionary statements**

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

**16.6 Training advisement**

Not available

**16.7 Notice for user(s)**

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the Magis-Pharma NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. Magis-Pharma NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

**16.8 Department issuing MSDS**

Magis-Pharma NV

[info@magis-pharma.be](mailto:info@magis-pharma.be)