

Tobramycin sulfate

Safety Data Sheet

632589

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU)

2015/830

Version: 2.0

Date of issue: 12/12/2011 Revision date 28/02/2020

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Substance
 Substance name : Tobramycin sulfate
 EC-No. : 256-499-2
 CAS-No. : 49842-07-1
 Product code : 632589
 Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical
 Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals
 Function or use category : Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
 A. Hofmanweg 71
 2031BH Haarlem - The Netherlands
 T +31(0)23-5319093
farma@duchefa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
 +31(0)23-5319093 (M-F 09:00-17:00)
 +31(0)6-30109355 (outside office hours)

Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (dermal), Category 4 H312
 Acute toxicity (inhalation:dust,mist) Category 4 H332
 Reproductive toxicity, Category 1B H360

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Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] Extra labelling to display Extra classification(s) to display

Hazard pictograms (CLP)

:



GHS08



GHS07

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H312 - Harmful in contact with skin.

H332 - Harmful if inhaled.

H360 - May damage fertility. May damage the unborn child..

Precautionary statements (CLP)

: P280 - Wear eye protection, face protection, protective clothing, protective gloves.

P302+P352 - IF ON SKIN: Wash with plenty of water/...

P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P308+P313 - IF exposed or concerned: Get medical advice.

P312 - Call a POISON CENTER/doctor if you feel unwell.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Tobramycin sulfate	(CAS-No.) 49842-07-1 (EC-No.) 256-499-2		Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation:dust,mist) , H332 Repr. 1B, H360

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: Remove victim to fresh air Seek medical advice.
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 Seek medical advice.
First-aid measures after eye contact	: Rinse immediately with plenty of water Seek medical advice.
First-aid measures after ingestion	: If you feel unwell, seek medical advice.

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

Symptoms/effects	: Damage to kidneys.
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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	: Dry powder Carbon dioxide Foam Water spray.
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5.2. Special hazards arising from the substance or mixture

Fire hazard	: On exposure to high temperature, may decompose, releasing toxic gases. Carbon monoxide. Nitrogen oxides. Sulphur oxides.
Explosion hazard	: Product is not explosive.

5.3. Advice for firefighters

Firefighting instructions	: Prevent fire fighting water from entering the environment.
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

6.1.1. For non-emergency personnel

Emergency procedures	: Ensure adequate air ventilation. Evacuate area.
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6.1.2. For emergency responders

Protective equipment	: [In case of inadequate ventilation] wear respiratory protection. Wear suitable protective clothing and eye/face protection.
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6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up dry powder and dispose properly.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

No additional information available

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area
Keep container tightly closed.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Hand protection:

Wear suitable gloves resistant to chemical penetration

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing.

Respiratory protection:

Dust production: dust mask with filter type P3

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Powder.
Molecular mass	: 1425.5 g/mol
Colour	: White.
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available

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Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Water: 50 g/l
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: 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

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Harmful in contact with skin. Harmful if inhaled.

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : May damage fertility. May damage the unborn child..

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STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information**12.1. Toxicity**

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Waste treatment methods : Avoid release to the environment.

Product/Packaging disposal : Dispose in a safe manner in accordance with local/national recommendations regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
Not applicable	Not applicable
14.2. UN proper shipping name	
Not applicable	Not applicable
14.3. Transport hazard class(es)	
Not applicable	Not applicable
Not applicable	Not applicable
14.4. Packing group	
Not applicable	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user

. Overland transport

No data available

- Air transport

No data available

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Tobramycin sulfate is not on the REACH Candidate List

Tobramycin sulfate is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Full text of H- and EUH-statements:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Repr. 1B	Reproductive toxicity, Category 1B
H312	Harmful in contact with skin.
H332	Harmful if inhaled.
H360	May damage fertility or the unborn child.

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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.