

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Reference number: T0153

Issue date: 30/05/2024 Revision date: 30/05/2024 Supersedes version of: 28/05/2024 Version: 3.1

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

### 1.1. Product identifier

Product form : Substance  
Trade name : Tobramycin sulphate  
EC-No. : 256-499-2  
CAS-No. : 49842-07-1  
Product code : T0153  
Formula : (C18H37N5O9)2·5H2SO4  
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 : Professional use  
Industrial/Professional use spec : For professional use only. Duchefa Biochemie B.V. products are intended only for "in vitro laboratory" research purposes.

#### 1.2.2. Uses advised against

No additional information available

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

Duchefa Biochemie B.V.  
A. Hofmanweg 71  
2031 BH Haarlem  
The Netherlands  
T +31(0)23-5319093 - F +31(0)23-5318027  
[info@duchefa.nl](mailto:info@duchefa.nl)

### 1.4. Emergency telephone number

Emergency number : Supplier contact information:  
+31(0)23-5319093 (M-F 09:00-17:00)  
+31(0)6-30008100 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
	World Health Organization world directory of poison centres	<a href="http://apps.who.int/poisoncentres/">http://apps.who.int/poisoncentres/</a>		Consult website for a local poison centre
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	

## 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 (inhal.), Category 4 H332  
Acute toxicity (inhalation:dust,mist) Category 4 H332

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Reproductive toxicity, Category 1B

H360

Full text of H- and EUH-statements: see section 16

### Adverse physicochemical, human health and environmental effects

May damage fertility or the unborn child. Harmful in contact with skin. Harmful if inhaled.

## 2.2. Label elements

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

Hazard pictograms (CLP)



GHS07

GHS08

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H312+H332 - Harmful in contact with skin or if inhaled.  
H360 - May damage fertility or the unborn child.

Precautionary statements (CLP)

: P201 - Obtain special instructions before use.  
P261 - Avoid breathing dust.  
P280 - Wear protective clothing, eye protection, face protection.  
P308+P313 - IF exposed or concerned: Get medical advice/attention.  
P312 - Call a POISON CENTRE or doctor if you feel unwell.

## 2.3. Other hazards

No additional information available

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Comments

: Content: 634-739 µg/mg

Substance type

: Mono-constituent

Name	Product identifier	%
Tobramycin sulphate	CAS-No.: 49842-07-1 EC-No.: 256-499-2	100

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general : IF exposed or concerned: Get medical advice/attention. Call a poison center or a doctor if you feel unwell.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Call a poison center or a doctor if you feel unwell.

First-aid measures after skin contact : Wash skin with plenty of water. Take off contaminated clothing.

First-aid measures after eye contact : Rinse eyes with water as a precaution.

First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects : Damage to kidneys.

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

Treat symptomatically.

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### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam.

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

Hazardous decomposition products in case of fire : Under fire conditions, hazardous fumes will be present: - COx. - NOx. - SOx.

#### 5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

### SECTION 6: Accidental release measures

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

General measures : Evacuate area.

##### 6.1.1. For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment. Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

Emergency procedures : Only qualified personnel equipped with suitable protective equipment may intervene. Avoid breathing dust.

Measures in case of dust release : Use good housekeeping practices to avoid rendering dust airborne.

##### 6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

#### 6.2. Environmental precautions

Avoid release to the environment. Prevent product from entering drains. Notify authorities if product enters sewers or public waters.

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

Methods for cleaning up : Sweep up dry powder and dispose properly. Dispose in a safe manner in accordance with local/national regulations. Notify authorities if product enters sewers or public waters.

Other information : Dispose of materials or solid residues at an authorized site.

#### 6.4. Reference to other sections

For further information refer to section 8.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear personal protective equipment. Do not get in eyes, on skin, or on clothing. Use only outdoors or in a well-ventilated area. Avoid breathing dust.

Hygiene measures : Separate working clothes from town clothes. Launder separately. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

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

Storage conditions : Keep container tightly closed and dry. Store locked up. Store in a well-ventilated place. Store at room temperature.

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### 7.3. Specific end use(s)

For professional use only. Duchefa Biochemie B.V. products are intended only for "in vitro laboratory" research purposes.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

No additional information available

#### 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

No additional information available

#### 8.1.5. Control banding

No additional information available

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

##### Appropriate engineering controls:

Ensure good ventilation of the work station.

#### 8.2.2. Personal protection equipment

##### Personal protective equipment symbol(s):



##### 8.2.2.1. Eye and face protection

Eye protection			
Type	Field of application	Characteristics	Standard
Safety glasses	Dust		EN 166

##### 8.2.2.2. Skin protection

##### Skin and body protection:

Wear suitable protective clothing

Hand protection					
Type	Material	Permeation	Thickness (mm)	Penetration	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11		EN ISO 374

##### 8.2.2.3. Respiratory protection

Respiratory protection			
Device	Filter type	Condition	Standard
Dust mask	Type P3	Dust protection	EN 143

##### 8.2.2.4. Thermal hazards

No additional information available

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### 8.2.3. Environmental exposure controls

#### Environmental exposure controls:

Avoid release to the environment.

## SECTION 9: Physical and chemical properties

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

Physical state	: Solid
Colour	: White to off-white.
Appearance	: Powder.
Molecular mass	: 1425,4 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not applicable
Boiling point	: Not available
Flammability	: Non flammable.
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: 6 – 8
pH solution concentration	: 4 %
Viscosity, kinematic	: Not applicable
Solubility	: Water: 50 g/l
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

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### 10.5. Incompatible materials

Strong oxidizers.

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified  
Acute toxicity (dermal) : Harmful in contact with skin.  
Acute toxicity (inhalation) : Harmful if inhaled. Harmful if inhaled.

Tobramycin sulphate (49842-07-1)	
LD50 oral	> 10500 mg/kg mouse
LD50 dermal	1100 mg/kg
LC50 Inhalation - Rat (Dust/Mist)	1,5 mg/l/4h

Skin corrosion/irritation : Not classified  
pH: 6 – 8  
Serious eye damage/irritation : Not classified  
pH: 6 – 8  
Respiratory or skin sensitisation : Not classified  
Germ cell mutagenicity : Not classified  
Carcinogenicity : Not classified  
Reproductive toxicity : May damage fertility or the unborn child.  
STOT-single exposure : Not classified  
STOT-repeated exposure : Not classified  
Aspiration hazard : Not classified

Tobramycin sulphate (49842-07-1)	
Viscosity, kinematic	Not applicable

### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The substance/mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

#### 11.2.2. Other information

No additional information available

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.  
Hazardous to the aquatic environment, short-term (acute) : Not classified  
Hazardous to the aquatic environment, long-term (chronic) : Not classified

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### 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. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The substance/mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

### 12.7. Other adverse effects

Additional information : Avoid release to the environment. Prevent entry to sewers and public waters

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste treatment methods : Dispose in a safe manner in accordance with local/national regulations. Avoid release to the environment. Dispose of contents/container in accordance with licensed collector's sorting instructions.

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
<b>14.1. UN number or ID number</b>		
Not applicable	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>		
Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>		
Not applicable	Not applicable	Not applicable
<b>14.4. Packing group</b>		
Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>		
Not applicable	Not applicable	Not applicable
No supplementary information available		

### 14.6. Special precautions for user

#### Overland transport

Not applicable

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### Transport by sea

Not applicable

### Air transport

Not applicable

### 14.7. Maritime transport in bulk according to IMO instruments

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

##### REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

##### REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

##### REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

##### PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

##### POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

##### Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

##### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

##### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

#### 15.1.2. National regulations

##### France

Occupational diseases	
Code	Description
RG 31	Occupational diseases caused by aminoglycosides, including streptomycin, neomycin and their salts

##### Germany

- Water hazard class (WGK) : Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).
- Chemicals Prohibition Ordinance (ChemVerbotsV) : This product is subject to ChemVerbotsV Annex 2 Entry 1. The following requirements must be observed: authorization requirement (according to § 6 paragraph 1 sentence 1), basic requirements for carrying out the delivery (according to § 8 paragraph 1, 3 and 4), identification and documentation (according to § 9 paragraph 1 to 3) and exclusion of the shipping route (according to § 10).
- Hazardous Incident Ordinance (12. BImSchV) : Is not subject to the Hazardous Incident Ordinance (12. BImSchV)



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### Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed  
SZW-lijst van mutagene stoffen : The substance is not listed  
SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed  
SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : The substance is not listed  
SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

### Denmark

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product  
Pregnant/breastfeeding women working with the product must not be in direct contact with the product

## 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	Flammability	Added	
	Revision date	Modified	
	Supersedes	Modified	
	Substance type	Added	
	Regulatory framework	Added	
	Adverse health effects caused by endocrine disrupting properties	Added	
	Concentration of the solution used for the pH measurement	Added	
1.1	Product group	Added	
2.1	Adverse physicochemical, human health and environmental effects	Added	
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
2.2	Precautionary statements (CLP)	Modified	
3	Composition/information on ingredients	Modified	
4.1	First-aid measures general	Added	
4.1	First-aid measures after skin contact	Modified	
4.1	First-aid measures after inhalation	Modified	
4.1	First-aid measures after ingestion	Modified	
4.1	First-aid measures after eye contact	Modified	
4.3	Other medical advice or treatment	Added	
5.1	Suitable extinguishing media	Modified	
5.3	Protection during firefighting	Modified	

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Indication of changes			
Section	Changed item	Change	Comments
6.1	Protective equipment	Added	
6.1	Emergency procedures	Added	
6.2	Environmental precautions	Modified	
6.3	Other information	Added	
6.3	Methods for cleaning up	Modified	
6.4	Reference to other sections (8, 13)	Added	
7.1	Hygiene measures	Added	
7.1	Precautions for safe handling	Modified	
7.2	Storage conditions	Modified	
8.2	Environmental exposure controls	Added	
8.2	Appropriate engineering controls	Added	
9.1	Viscosity, kinematic	Added	
9.1	Freezing point	Added	
9.1	Flash point	Added	
9.1	Explosive limits (vol %)	Added	
9.1	Auto-ignition temperature	Added	
9.1	pH	Added	
9.1	Colour	Added	
10.1	Reactivity	Added	
10.3	Possibility of hazardous reactions	Added	
10.4	Conditions to avoid	Added	
10.6	Hazardous decomposition products	Added	
11.1	LD50 dermal	Added	
12.1	Ecology - general	Added	
12.1	LC50 Inhalation - Rat (Dust/Mist)	Added	
12.6	Adverse effects on the environment caused by endocrine disrupting properties	Added	
13.1	Waste treatment methods	Modified	
15.2	Chemical safety assessment	Added	
16	Abbreviations and acronyms	Modified	
16	Data sources	Modified	

Abbreviations and acronyms:	
ATE	Acute Toxicity Estimate
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor

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<b>Abbreviations and acronyms:</b>	
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
SDS	Safety Data Sheet
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

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### Data sources

: ECHA (European Chemicals Agency). Supplier's safety documents. REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

### Full text of H- and EUH-statements:

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

Safety Data Sheet (SDS), EU Duchefa 2023

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.