

Safety Data Sheet

according to Regulation (EU) 2015/830

Version: 2.0

Date of issue: 26/11/2010 Revision date: 11/10/2017

Supersedes 02/08/2011

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

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

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
World Health Organization world	http://apps.who.int/poisoncentres/	Consult website for a local poison centre
directory of poison centres		

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
Reproductive toxicity, Category 1B H360

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

Adverse physicochemical, human health and environmental effects

No additional information available

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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 gloves, protective clothing, face protection, eye

protection.

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

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Comments : Content: 634 µg/mg Name : Tobramycin sulphate

CAS-No. : 49842-07-1 EC-No. : 256-499-2

Name	Product identifier	%
Tobramycin sulphate	(CAS-No.) 49842-07-1	~ 100

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 : Assure fresh air breathing. Get medical advice/attention.

First-aid measures after skin contact : Get immediate medical advice/attention. 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 contact with eyes, rinse immediately with plenty of water and seek

medical advice.

First-aid measures after ingestion : Get medical advice/attention.

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

No additional information available

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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water. Dry chemical powder, alcohol-resistant foam, carbon dioxide (CO2).

Special hazards arising from the substance or mixture

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

case of fire

5.3. Advice for firefighters

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

respiratory protection.

Other information : Prevent fire fighting water from entering the environment.

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.

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

6.1.2. For emergency responders

No additional information available

6.2. **Environmental precautions**

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

: Sweep up dry powder and dispose properly. Dispose in a safe manner in Methods for cleaning up

accordance with local/national regulations.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed and dry.

Storage temperature : 2 - 8 °C

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

Control parameters 8.1.

No additional information available

according to Regulation (EU) 2015/830

8.2. Exposure controls

Hand protection:

Туре	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

Filter type P3 (EN 143)

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid

Appearance : Powder.

Molecular mass : 1425,4 g/mol

Colour

Odour : No data available
Odour threshold : No data available
pH : No data available
pH solution : 6 - 8 (40g/l 25°C)
Relative evaporation rate : No data available

(butylacetate=1)

Solubility

Melting point : No data available : No data available Freezing point : No data available **Boiling point** Flash point : No data available : No data available Auto-ignition temperature : No data available Decomposition temperature : No data available Flammability (solid, gas) : No data available Vapour pressure Relative vapour density at 20 °C : No data available Relative density : No data available

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

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: Water: 50 g/l

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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 : Dermal: Harmful in contact with skin. Inhalation: Harmful if inhaled.

Tobramycin sulphate (49842-07-1)	
LD50 oral	> 10500 mg/kg mouse
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 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

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

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12.5. Results of PBT and vPvB assessment

No additional information available

12.6. 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.

SECTION 14: Transport information

In accordance with ADR / IATA / IMDG

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

14.6. Special precautions for user

Overland transport

Not applicable

- Transport by sea

Not applicable

- Air transport

Not applicable

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 sulphate is not on the REACH Candidate List

Tobramycin sulphate is not on the REACH Annex XIV List

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15.1.2. National regulations

Germany

12th Ordinance Implementing the Federal Immission Control Act -12.BImSchV

: Is not subject of the 12. BlmSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen

: The substance is not listed

SZW-lijst van mutagene stoffen NIET-limitatieve lijst van voor de voortplanting giftige stoffen -

: The substance is not listed : The substance is not listed

Borstvoeding

NIET-limitatieve lijst van voor de voortplanting giftige stoffen -Vruchtbaarheid

: The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen -

: The substance is not listed

Ontwikkeling

Denmark

Recommendations Danish Regulation : 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

The requirements from the Danish Working Environment Authorities

regarding work with carcinogens must be followed during use and disposal

Chemical safety assessment 15.2.

No additional information available

SECTION 16: Other information

Indication of changes:

1.4	Emergency number	Modified	
2	Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]	Removed	Obsolete
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves

Abbreviations and acronyms:

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

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REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
SDS	Safety Data Sheet

Data sources

: ECHA (European Chemicals Agency). Supplier. 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. 3 (Oral)	Acute toxicity (oral), Category 3
Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
Repr. 1B	Reproductive toxicity, Category 1B
H301	Toxic if swallowed.
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

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