

## SAFETY DATA SHEET

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

#### 1.1. Product identifier

**Product name:** Tobramycin Sulfate

**CAS #:** 49842-07-1

**EC/List#:** 256-499-2

**INDEX #:** Not listed

**REACH reg. #:** not registered, exempted.

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

**Product Use:** Pharmaceutical product used as antibiotic agent.

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

Manufacturer & Distributor

Xellia Pharmaceuticals ApS

Dalslandsgade 11

2300 Copenhagen S.

Denmark

+45 3264 5500

Responsible person for the safety data sheet (e-mail): sales@xellia.com

#### 1.4. Emergency telephone number

**Poison Control Center (USA):** +1 877 800 5553

**CHEMTREC (USA Transportation):** +1 800 424 9300

**CANUTREC (Canadian Transportation):** +1 613 996 6666

<http://apps.who.int/poisoncentres/>

### SECTION 2: Hazards identification

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

Classification according to Regulation (EC) No 1272/2008:

Acute Tox. 4 (Inhal.) Acute Tox. 4 (Oral) Repr. 1B

#### 2.2. Label elements



DANGER

H302: Harmful if swallowed.

H332: Harmful if inhaled.

H360: May damage fertility or the unborn child.

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.  
 P302+P352: IF ON SKIN: wash with plenty of water.

P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
 P317: Get emergency medical help.  
 P318: if exposed or concerned, get medical advice.  
 P362+P364: Take off contaminated clothing and wash it before reuse.  
 P405: Store locked up.  
 P501: Dispose of contents/container appropriately.

### 2.3. Other hazards

The substance is not considered PBT/vPvB according to criteria in Annex XIII neither has properties of endocrine disruption.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Active component	CAS #	EC/List #
Tobramycin Sulfate	49842-07-1	256-499-2

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

**General information:** Remove the injured person from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health practitioner or other licensed health care provider familiar with chemical exposure in the workplace. If the person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons with severe hypersensitivity (anaphylactic) reactions should receive immediate medical attention.

**Eye contact:** Flush eyes for 15 minutes with plenty of water. Remove contact lenses, if any, and this is easy to do. Continue rinsing. Consult a specialist if irritation develops and persists.

**Skin contact:** Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation or rash develops. In case of eczema or other skin diseases, consult a doctor.

**Ingestion:** After ingestion of large amounts, call a poison center or doctor. Do not induce vomiting. Wash your mouth. Do not give anything orally to an unconscious person. Consult a doctor if symptoms occur. When vomiting, keep your head low so that stomach contents do not get into the lungs.

**Inhalation:** The person concerned should be taken out to fresh air and placed in a resting position such that he or she can breathe easily. If the injured person is unconscious and not breathing: Ensure that there are no obstructions in the airways and have artificial respiration performed by appropriately trained persons. If necessary, apply external heart massage and consult a doctor. If breathing remains difficult, consult a doctor.

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

**Symptoms and Effects of Exposure:** None.

**Medical Conditions Aggravated by Exposure:** None

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

General support measures, symptomatic treatment.

**In case of discomfort or unconsciousness:** Show this safety data sheet to a physician or emergency center, treat symptomatically.

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## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Water, carbon dioxide, dry chemical, foam, or other alternatives.  
Fire extinguishing agents not suitable for safety reasons: none.

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

**General hazards:** May be combustible at high temperature.

**Hazardous combustion products:** May be combustible at high temperature. Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

**Unsuitable extinguishing media:** None

**Specific methods:** Not available.

### 5.3. Advice for firefighters

Wear appropriate protective equipment. Use water spray to cool unopened containers. As with any fire, evacuate personnel to a safe area.

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## SECTION 6: Accidental release measures

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

Keep away unnecessary staff. Wear appropriate protective equipment. Avoid inhaling dust from spills. Do not touch damaged containers or spills unless you wear appropriate protective clothing. Ensure adequate ventilation. Dust deposits should not accumulate on surfaces, as they can form explosive mixtures if released into the atmosphere in appropriate concentrations. For personal protection, see Section 8 of the Safety Data Sheet.

### 6.2. Environmental precautions

**Water spill:** In case of intrusion into inland waters or sewers, notify the competent authorities. Do not allow to enter sewer/surface water/groundwater.

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

Vacuum material with appropriate dust collection in place. Be aware of potential for dust explosion when using electrical equipment. If a vacuum is not available, lightly mist material and remove by sweeping or wet wiping. Wear appropriate equipment including eye protection, to avoid exposure.

Release notes: If the spill could potentially enter any waterway, including intermittent dry creeks, contact the local authorities.

### 6.4. Reference to other sections

See section 1 for emergency contact information, section 8 for personal protective equipment details, and section 13 for disposal information.

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## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

**For large quantities:** Engineering controls are recommended to ensure adequate ventilation such that exposures do not exceed TWA for an eight-hour exposure. With adequate ventilation, respiratory protection may not be needed. In the absence of adequate ventilation, suitable respiratory protection is required. The need for additional personal protective equipment including respirators, eye and skin protection should be based on a job-specific risk

assessment. Additional personal protective equipment may include chemical-resistant gloves and body covering, goggles, and face shield. Adequate eye protection is always required.

**For small quantities:** Keep dry and away from sources of ignition.

**Work hygienic practices:** Keep the container tightly closed when not use. Facilities storing or using this material should be equipped with an emergency eyewash and safety shower. Good personal hygiene practices should always be followed.

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

Store securely, inaccessible for unauthorized persons. Keep dry and away from sources of ignition.

Store below 25°C (77°F) in original, unopened package or container.

### 7.3. Specific end use(s)

See section 1.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

OEL for the substance: 0.22 mg/m3.

### 8.2. Exposure controls

**Appropriate engineering controls:**

For laboratory operations, use a local exhaust ventilation or ventilated chamber for high-energy operations such as shredding. Choose and use enclosed equipment and personal protective equipment based on the risk assessment. During transportation, cover all containers for storing solutions and suspensions. In case of dust generation, exhaust ventilation or ensuring general ventilation of the room.

**Personal protective equipment:**

**Eyes protection:** If contact is likely, safety glasses with lateral protection must be used.

**Hand protection:** Wear chemically resistant gloves (tested according to EN 374) while completing training specific to the specific activity. The gloves should be regularly inspected and replaced for wear, tearing or contamination.

**Skin:** Laboratory clothes.

**Respiratory protection:** As a rule, a respirator is not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters to clean spills. Respiratory protection adapted to the task and the level of existing technical controls.

**Comments:** This material may cause sensitization or an allergic response with minimal exposure.

Under conditions of overexposure, the material may be hazardous.

## SECTION 9: Physical and chemical properties

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

a)	Physical state	solid powder
b)	Color	white to off-white
c)	Odor	odorless
d)	Melting point/freezing point	not available
e)	Boiling point or starting boiling point and boiling point range	not applicable for solids
f)	Flammability	can be burned but not classified

g)	Upper/lower flammability or explosive limits	not applicable for solids
h)	Flash point	not applicable for solids
i)	Auto-ignition temperature	not available
j)	Decomposition temperature	not available
k)	pH	not available
l)	Kinematic viscosity	not available
m)	Solubility	soluble in water
n)	Partition coefficient: N-octanol/water (log value)	-5.8 (calculated value)
o)	Vapor pressure	<0,0000001 kPa at 25 oC (calculated value)
p)	Density and/or relative density	not available
q)	Relative vapor density	not applicable for solids
r)	Particle characteristics	not available

## 9.2. Other information

No further relevant information is available.

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No data available.

### 10.2. Chemical stability

Stable when used as intended.

### 10.3. Possibility of hazardous reactions

Under normal conditions, they are not known.

### 10.4. Conditions to avoid.

Incompatible materials, dust generation, excess heat, alkaline materials, strong oxidants, exposure to moist air or water.

### 10.5. Incompatible materials

Strong oxidants, moisture.

### 10.6. Hazardous decomposition products

Nitrogen oxides, carbon monoxide, carbon dioxide.

## SECTION 11: Toxicological information

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

#### a) Acute toxicity

Acute oral LD50: >10 500 mg/kg (mouse), >7500 mg/kg (rat). Subcutan or intraperitoneal administration gives LD50 for mouses and rats 367-1030 mg/kg values. That is why the product is classified.

- b) Skin corrosion/skin irritation:** Slight irritant. Based on available data, the classification criteria are not met.
- c) Severe eye damage/irritation:** Slight irritant. Based on available data, the classification criteria are not met.
- d) Respiratory or skin sensitization:** Sensitizer. Based on available data, the classification criteria are not met.
- e) Germ cell mutagenicity:** Ames bacterial reversion test was negative as well as a mouse lymphoma forward mutation assay. Based on available data, the classification criteria are not met.
- f) Carcinogenicity:** A two-year rat inhalation toxicology study rats were exposed to tobramycin inhalation solution for up to 1.5 hours/day for 95 weeks. Measured serum level of tobramycin was measured up to 35 µg/ml and classified. There was no drug-related increase in the incidence of any variety of tumors. Based on available data, the classification criteria are not met.
- g) Reproductive toxicity:** There have been several studies on the reprotoxic effects of tobramycin with mice, rats, guinea pigs with no negative signs. However, it proved the tobramycin crossed the term placenta in humans. Among 6 pregnancies one child was diagnosed with neural tube defect, and another child was diagnosed with cleft lip/palate. Repr. 1B classification.
- h) Single post-exposure specific target organ toxicity (STOT):** Based on available data, the classification criteria are not met.
- i) Specific target organ toxicity (STOT) after repeated exposure:**  
Not classified, however may cause damage in kidney and hearing organ. Based on available data, the classification criteria are not met.
- j) Aspiration hazard:** Based on its chemical structure, the product is not classified.

## 11.2. Information on other hazards:

Pharmacologically active substance.

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## SECTION 12: Ecological information

### 12.1. Toxicity

Not available

### 12.2. Persistence and degradability

No applicable information found. Releases to the environment should be avoided.

### 12.3. Bioaccumulative potential

No applicable information found.

### 12.4. Mobility in soil

No applicable information found.

### 12.5. Results of PBT and vPvB assessment

The substance shall not be considered PBT/vPvB according to the criteria in Annex XIII.

### 12.6. Endocrine disrupting properties

No such properties are known to the substance.

### 12.7. Other adverse effects

The substance is possibly harmful for the aquatic environment, due to its antibiotic properties.

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## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Do not empty into drain. Dispose of any cleanup materials and waste residue according to applicable laws and regulations.

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## SECTION 14: Transport information

### 14.1. UN Number or ID number

Not Regulated.

### 14.2. UN proper shipping name

Not Regulated.

### 14.3. Transport hazard class(es)

Not Regulated.

### 14.4. Packing group

Not Regulated.

### 14.5. Environmental hazards

Not Regulated.

### 14.6. Special precautions for user

Not Regulated.

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

Not relevant.

USA DOT (DEPARTMENT OF TRANSPORTATION)

**Proper Shipping Name:** Not regulated.

CANADA TRANSPORT OF DANGEROUS GOODS

**Proper Shipping Name:** Not regulated.

AIR (ICAO/IATA)

**Proper Shipping Name:** Not regulated.

VESSEL (IMO/IMDG)

**Proper Shipping Name:** Not regulated.

EUROPEAN TRANSPORTATION:

**ADR/RID HAZARD CLASSIFICATION:** Not Regulated.

U.S. CUSTOMS HARMONIZATION NUMBER: Not Available.

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## SECTION 15: Regulatory information

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

#### EUROPEAN UNION

**Council Directive 94/33/EC** of 22 June 1994 on the protection of young people at work:

Must not be used by persons under 18 years of age.

**Council Directive 92/85/EEC** of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding: The employer shall assess the working conditions and, if there is any risk to the safety or health and any effects on the pregnancy or breastfeeding of workers, take the necessary measures to adjust the working conditions.

**Implementation of directive 2001/82/EC of the European Parliament and of the council of 6 November 2001 in the Community code relating to veterinary medical products:**

Denmark: The Danish Medicines Agency (Lægemiddelstyrelsen) must be notified that this substance is produced, imported, exported, stored, sold, delivered, packed, possessed or in other ways handled in Denmark (Bekendtgørelse nr. 1226 af 7 December 2005 om omgang med visse stoffer og produkter hvis indhold kan anvendes som lægemidler til dyr.).

For other countries: Please contact national authorities regarding notification of the substance.

**UNITED STATES FEDERAL REGULATIONS**

**Superfund Amendments and Reauthorization Act (SARA) Title III 311/312 hazard categories:**

**Fire:** No      **Pressure generating:** No      **Reactivity:** No      **Acute:** No      **Chronic:** No

**313 Reportable Ingredients:** Not Listed

**Title III notes:**

**Comprehensive Response, Compensation, and Liability Act (CERCLA)**

**CERCLA RQ:** Not listed.

**Toxic Substances Control Act (TSCA)**

**TSCA Regulatory:** Exempt

**National Response Center:** US Coast Guard National Center Response Telephone +1 800 424 8802.

**UNITED STATES STATE REGULATIONS**

**California Proposition 65:** This product does not contain chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

**CANADA**

Workplace Hazardous Material Information System (WHMIS) hazard symbol and classification

**WHMIS Controlled:** Not regulated.

**Canadian Environmental Protection Act:** Not listed.

**15.2. Chemical safety assessment**

No CSR is compiled because the substance is exempted.

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**SECTION 16: Other information**

**Reason for issue:** Update to include 2020/878 EU Commission regulation. Updated some physical parameters.

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