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

· **Informations to product No. 5245**

· **Product name:**

**Gentamicinsulfat, API (mikrobielle Herkunft)**  
Gentamicini sulfas

· **Supplier of the Product / responsible Company:**

Caesar & Loretz GmbH

Herderstr. 31

40721 Hilden

Tel.: 02103/4994-0

Fax: 02103/32360

e-mail: info@caelo.de

· **Emergency telephone:**

Giftinformationszentrum Mainz

Langenbeckstr. 1, 55131 Mainz

Tel.: 06131/19240

· **Relevant identified uses of the substance or mixture and uses advised against:**

No further relevant information available.

· **Application of the substance / mixture:**

Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.

## 2 Hazards identification

· **GHS-Labeling Elements:**



· **Signal word:** Danger

· **H-Phrases:**

H317 May cause an allergic skin reaction

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled

· **P-Phrases:**

P280 Wear protective gloves/protective clothing/eye protection/face protection


P260 Do not breathe dust/fume/gas/mist/vapours/spray

P302 IF ON SKIN

P352 Wash with soap and water

**Skin Sens. 1**

**Resp. Sens. 1**

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### 3 Composition / information on ingredients

**CAS-No. Substance name**

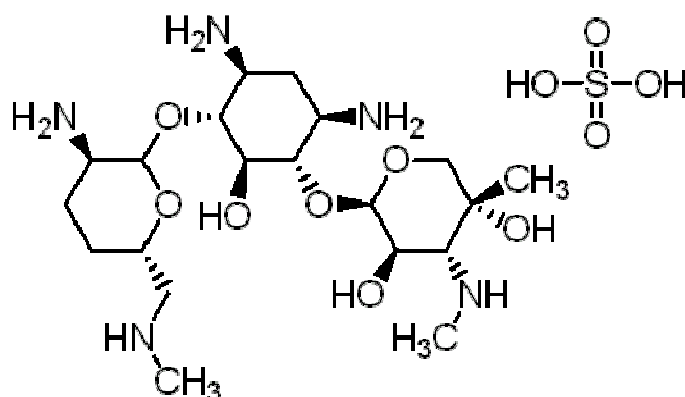
1405-41-0 Gentamicin sulphate

• **EINECS-No.:** 215-778-9

• **REACH Reg. No.:** (pre-registered)

• **INCI-Name:** -

• **Chemical characterization:**



### 4 First aid measures


- **after inhalation:** Bring the person out of the contaminated area to fresh air, Seek medical help immediately. Show product-label or this MSDS.
- **After skin contact:** Take off contaminated clothes and shoes, wash immediately with plenty of water and soap.
- **After eye contact:** Rinse out with plenty of water with the eyelid wide open. If eye irritation persists, call in ophthalmologist.
- **after swallowing:** Drink plenty of water. Induce vomiting, seek medical advice.

### 5 Fire-fighting measures

- **Suitable extinguishing media:** All regular extinguishing media can be used. Select fire fighting measures suitable to surrounding environment.
- **Specific hazards during fire fighting:** Combustible. In case of fire dangerous vapours/gases can be generated: Smoke gases.
- **Special protective equipment for fire-fighters:** Suitable protective clothes and respiratory protection.
- **Additional information:** Prevent fire extinguishing water from contaminating surface water, the ground water system or soil. Residues must be deposited according to local regulations.

### 6 Accidental release measures:

- **Personal protective measures:** Avoid contact with substance.
- **Environmental protective measures:** Prevent from entering into drains.
- **Methods for cleaning:** Take up dry. Disposal according to Chapter 13 of this MSDS. Clean up with water.

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## 7 Handling and storage

- **Handling:** Avoid dust formation. Avoid inhalation of dust.
- **Advice on safe handling:** Ensure good ventilation/exhaustion at the workplace. Handling corresponding to laboratory safety guidelines.
- **Informations to fire or explosion protection:** No special measures required.
- **Requirements for storage areas and containers:** Tightly closed. Store at a dry place. At room temperature ( +15°C to +25°C ).
- **Additional informations to storage conditions:** Keep container tightly closed.

## 8 Exposure controls / personal protective equipment

- **Personal protective equipment:**
- **General protective and hygiene measures:**  
Keep away from food, beverages and animal food.  
Take off contaminated clothes immediately.  
Avoid contact with eyes and skin.
- **Respiratory protection:** Dust protection mask.
- **Hand protection:** Protection gloves of rubber.
- **Eye protection:** Safety glasses.

## 9 Physical and chemical properties


- **Form:** solid
- **Colour:** white
- **Odour:** odourless
- **Melting point / melting range:** 218 – 237 °C
- **Boiling point / boiling range:** not determined
- **Density:** not determined
- **Solubility in / Miscibility with**
- **Water:** soluble
- **pH-value/range:** (40g / l) 3,5 – 5,5

## 10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:** No decomposition during appropriate use.
- **Hazardous reactions:** No hazardous reactions known.
- **Hazardous decomposition products:** None if used appropriately.

## 11 Toxicological information

- **Acute toxicity:** RTECS: LY2625000  
LD50 > 5000 mg/kg rat (oral)  
LD50 630 mg/kg rat (i.p.)  
LD50 96 mg/kg rat (i.v.)  
LD50 873 mg/kg (Base) rat (s.c.)  
LD50 11269 mg/kg mouse (oral)  
LD50 245 mg/kg mouse (i.p.)

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LD50 47 mg/kg mouse (i.v.)

LD50 478 mg/kg mouse (s.c.)

- **Primary irritant effect:**
- **on skin:** Irritant effect.
- **on eyes:** Irritant effect with allergic reactions possible.
- **on respiratory organs:** Irritations of mucous membranes, Coughing, Respiratory insufficiency.
- **Sensitization:** Sensitization by inhalation and skin contact possible.

## 12 Ecological information

- **Information about elimination (persistence and degradability):** Quantitative data about ecological effects of this product are not available. Ecotoxic effects are possible.
- **General advices:** Do not allow to enter surface and ground water, waste water or soil.
- **Water hazard class:** 2 (self classification): hazardous for water.

## 13 Disposal considerations

- **Product:**
- **Recommendation:** Disposal according to local regulations as pharmaceutical waste.
- **Empty contaminated packaging:**
- **Recommendation:** Disposal according to the local regulations.

## 14 Transport informations

- **Land transport according to ADR:**  
Not classified as dangerous in the meaning of transport regulations.

## 15 Regulatory information

- **Labelling according to actual legislation (GHS, Globally Harmonized System of Classification and Labelling of Chemicals):**

The product is classified and labelled according to GHS-regulations.

- **Hazard symbols:** GHS08

- **Signal word:** Danger

- **H-Phrases:**

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P280 Wear protective gloves/protective clothing/eye protection/face protection

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- **Labelling according to EC-regulations:**

- **National regulations (Germany):**

- **Water hazard class:** see chapter 12

- **Storage class TRGS 510:** 11

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## 16 Other Information

The information provided in this MSDS is correct to the best of our knowledge at the date of edition.

· **Reason for last revision:** Adjustment to regulation (EC) 1907/2006 (REACH) and GHS-labelling system.