

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 14.04.2011

Revision: 14.04.2011

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

\***Product identifier** Gentamicin sulfate

\***Name:** GENTAMICIN SULFATE

\***Article number:** 634650

\***CAS Number:** 1405-41-0

\***EINECS Number:**

215-778-9

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

\***Application of the substance / the preparation** Pharmaceutical active substance

\***Details of the supplier of the safety data sheet**

\***Manufacturer/Supplier:**

DOLDER AG  
Immengasse 9  
CH-4004 Basel  
Switzerland

\***Further information obtainable from:**

Dr.Christian Schulz ++41 61 326 63 32

christian.schulz@dolder.com

MO-FR 8.30-12.00/13.00-16.30

\***Emergency telephone number:** Dr. Christin Schulz Tel. ++41 61 326 63 32 (24 h)

### 2 Hazards identification

\***Classification of the substance or mixture**

\***Classification according to Regulation (EC) No 1272/2008**



GHS08 health hazard

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.



GHS07

Skin Sens. 1 H317 May cause an allergic skin reaction.

\***Classification according to Directive 67/548/EEC or Directive 1999/45/EC**



Xn; Sensitising

R42/43: May cause sensitisation by inhalation and skin contact.

\***Information concerning particular hazards for human and environment:** N/A

\***Label elements**

\***Labelling according to Regulation (EC) No 1272/2008**

The substance is classified and labelled according to the CLP regulation.

\***Hazard pictograms** GHS08

\***Signal word** Danger

\***Hazard statements**

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

H317 May cause an allergic skin reaction.

\***Precautionary statements**

P285 In case of inadequate ventilation wear respiratory protection.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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

P321 Specific treatment (see on this label).

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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- \***Other hazards**
- \***Results of PBT and vPvB assessment**
- \***PBT:** Not applicable.
- \***vPvB:** Not applicable.

### **3 Composition/information on ingredients**

- \***Chemical characterization:** Substances
- \***CAS No. Description:**  
GENTAMICIN SULFATE
- \***Identification number(s):** N/A
- \***EINECS Number:** 215-778-9

### **4 First aid measures**

- \***Description of first aid measures**
- \***General information** Immediately remove any clothing soiled by the product.
- \***After inhalation**  
Supply fresh air and to be sure call for a doctor.  
In case of unconsciousness place patient stably in side position for transportation.
- \***After skin contact** Immediately wash with water and soap and rinse thoroughly.
- \***After eye contact** Rinse opened eye for several minutes under running water.
- \***After swallowing**  
Rinse out mouth and then drink plenty of water.  
Seek medical treatment.
- \***Information for doctor**
- \***Most important symptoms and effects, both acute and delayed** No further relevant information available.
- \***Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### **5 Firefighting measures**

- \***Extinguishing media**
- \***Suitable extinguishing agents**  
Water spray  
Foam  
Carbon dioxide  
Fire-extinguishing powder
- \***For safety reasons unsuitable extinguishing agents** Water with full jet.
- \***Special hazards arising from the substance or mixture**  
Carbon monoxide (CO)  
Carbon dioxide  
Sulfur oxides (SOx)
- \***Advice for firefighters**
- \***Protective equipment:** Wear self-contained respiratory protective device.
- \***Additional information**  
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

### **6 Accidental release measures**

- \***Personal precautions, protective equipment and emergency procedures**  
Avoid formation of dust.  
Ensure adequate ventilation  
Wear protective equipment. Keep unprotected persons away.
- \***Environmental precautions:** Do not allow product to reach sewage system or any water course.

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**\*Methods and material for containment and cleaning up:***Pick up mechanically.**Dispose of the material collected according to regulations.***\*Reference to other sections***See Section 7 for information on safe handling**See Section 8 for information on personal protection equipment.**See Section 13 for disposal information.*

### 7 Handling and storage

**\*Handling****\*Precautions for safe handling***Ensure good ventilation/exhaustion at the workplace.**Open and handle receptacle with care.***\*Information about fire - and explosion protection:** *The product is not flammable***\*Conditions for safe storage, including any incompatibilities****\*Storage****\*Requirements to be met by storerooms and receptacles:** *Store only in the original receptacle.***\*Information about storage in one common storage facility:** *Store away from oxidizing agents.***\*Further information about storage conditions:** *This product is hygroscopic.***\*Specific end use(s)** *No further relevant information available.*

### 8 Exposure controls/personal protection

**\*Additional information about design of technical facilities:** *No further data; see item 7.***\*Control parameters****\*Ingredients with limit values that require monitoring at the workplace:** *Not required.***\*Additional information:** *The lists valid during the making were used as basis.***\*Exposure controls****\*Personal protective equipment****\*General protective and hygienic measures***Keep away from foodstuffs, beverages and feed.**Immediately remove all soiled and contaminated clothing**Wash hands before breaks and at the end of work.***\*Respiratory protection:***In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.***\*Protection of hands:***Protective gloves.**The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.**Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.**Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation***\*Material of gloves***Nitrile rubber, NBR**The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.***\*Penetration time of glove material***The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.*

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**\*Eye protection:** Use safety goggles.**\*Body protection:** Protective work clothing.

### 9 Physical and chemical properties

#### \*Information on basic physical and chemical properties

##### \*General Information

##### \*Appearance:

<b>Form:</b>	Powder
<b>Colour:</b>	Cream coloured
<b>*Odour:</b>	Odourless
<b>*Odour threshold:</b>	Not determined.

<b>*pH-value at 20°C:</b>	3.8-4.2
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##### \*Change in condition

<b>Melting point/Melting range:</b>	218-237°C
<b>Boiling point/Boiling range:</b>	N/A

<b>*Flash point:</b>	Not applicable
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<b>*Flammability (solid, gaseous)</b>	Not applicable.
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<b>*Decomposition temperature:</b>	Not determined.
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<b>*Self-igniting:</b>	Not determined.
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<b>*Danger of explosion:</b>	Product does not present an explosion hazard.
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##### \*Explosion limits:

<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.

<b>*Vapour pressure:</b>	Not determined.
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<b>*Density:</b>	Not determined
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<b>*Relative density</b>	Not determined.
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<b>*Vapour density</b>	Not determined.
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<b>*Evaporation rate</b>	Not applicable.
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<b>*Solubility in / Miscibility with Water at 20°C:</b>	1000 g/l
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<b>*Segregation coefficient (n-octanol/water):</b>	Not determined.
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##### \*Viscosity:

<b>dynamic:</b>	Not determined.
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<b>kinematic:</b>	Not determined.
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<b>*Other information</b>	No further relevant information available.
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### 10 Stability and reactivity

#### \*Reactivity

##### \*Chemical stability

**\*Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

**\*Possibility of hazardous reactions** No dangerous reactions known

**\*Conditions to avoid** No further relevant information available.

**\*Incompatible materials:** No further relevant information available.

##### \*Hazardous decomposition products:

Carbon monoxide and carbon dioxide

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Sulphur oxides (SOx)

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**11 Toxicological information****\*Information on toxicological effects****\*Acute toxicity:**

Oral	LD50	630 mg/kg (rat)
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**\*LD/LC50 values relevant for classification:**

Oral	LD50	11269 mg/kg (mouse)
		>5000 mg/kg (rat)
Inhalative	LC50/4h	>0.20 (mg/l) (rat)
	LD50 ipr	245 mg/kg (mouse)
		630 mg/kg (rat)
	LD50 ivn	47 mg/kg (mouse)
		96 mg/kg (rat)

**\*Primary irritant effect:****\*on the skin:** No irritant effect.**\*on the eye:** No irritating effect.**\*Sensitization:**

Sensitization possible through inhalation.

Sensitization possible through skin contact.

**12 Ecological information****\*Toxicity****\*Aquatic toxicity:** No further relevant information available.**\*Persistence and degradability** No further relevant information available.**\*Bioaccumulative potential** No further relevant information available.**\*Mobility in soil** No further relevant information available.**\*Results of PBT and vPvB assessment****\*PBT:** Not applicable.**\*vPvB:** Not applicable.**\*Other adverse effects** No further relevant information available.**13 Disposal considerations****\*Waste treatment methods****\*Recommendation**

Disposal must be made according to official regulations.

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

**\*Uncleaned packaging:****\*Recommendation:** Disposal must be made according to official regulations.**14 Transport information****\*Land transport ADR/RID (cross-border)****\*ADR/RID class:** Not restricted**\*Maritime transport IMDG:****\*Marine pollutant:** No**\*Special precautions for user** Not applicable.**\*Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

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**15 Regulatory information**

**\*Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**16 Other information**

*This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.*

**\*Department issuing MSDS:** Documentation

**\*Contact:**

*Dr. Christian Schulz (General information / Emergency information)*

*Tel. ++41 61 326 63 32 (24 h) / Fax ++41 61 321 01 81 (Office hrs)*

*Dr. Marco Pickel (Technical information)*

*Tel. ++41 326 65 12 (Office hrs)*

**\*Abbreviations and acronyms:**

*ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)*

*RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)*

*IMDG: International Maritime Code for Dangerous Goods*

*GHS: Globally Harmonized System of Classification and Labelling of Chemicals*

*EINECS: European Inventory of Existing Commercial Chemical Substances*

*CAS: Chemical Abstracts Service (division of the American Chemical Society)*

*LC50: Lethal concentration, 50 percent*

*LD50: Lethal dose, 50 percent*

**\*\* Data compared to the previous version altered.**

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