

Safety Data Sheet (US)

Federal Hazard Communication Standard (29 CFR 1910.1200)

Date of issue: 13-MAR-2018

Replaces version of:

Gentamicin, sulfate



Section 1: Identification

Product name	Gentamicin, sulfate
Chemical Name	Gentamicin, sulfate
Synonyms	Gentamicin, sulfate
CAS Number	1405-41-0
Usage	Pharmaceutical active ingredient
Company name	Novartis Pharma AG 4002 Basel Switzerland Tel: +41 61 324 11 11, email: sds.support@novartis.com
Emergency phone number	CHEMTEL (International) +1 813 676 1670 (365/24/7)

Section 2: Hazards identification

GHS hazard category

Acute Toxicity (oral): Cat.4

Acute Toxicity (dermal): Cat.4

Acute Toxicity (inhalation): Cat.4

Flammable solid: not classified

Explosives, oxidizing, self-reactive or self-heating, pyrophoric substances, substances which in contact with water emit flammable gases, organic peroxides: Not classified: Expert statement

Signal Word: Self assessment according REGULATION (EC) No 1272/2008



Warning

Hazard statements
H302: Harmful if swallowed.
H312: Harmful in contact with skin.
H332: Harmful if inhaled.

Precautionary statements
P302/352/312: IF ON SKIN: Wash with plenty of soap and water. Call a POISON CENTER or doctor/physician if you feel unwell.
P304/340/312: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.
P301/330/312: IF SWALLOWED: Rinse mouth. Call a POISON CENTER or doctor/physician if you feel unwell.

Other hazards

Specific hazards None known

Section 3: Composition / information on ingredients

Chemical characterisation of the substance / preparation:

Type	Substance
Chemical Class	aminoglycoside antibiotic
Chemical Name	Gentamicin, sulfate
CAS Number	1405-41-0
Content:	100 %

For TLV values of declared components, see Section 8, Exposure controls / Personal

Full text of H-Phrases see under Section 16

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Section 4: First aid measures

General Information	Protection is needed for the First Aider. Remove the victim from danger zone, avoid further exposure.
Inhalation	After inhalation move to fresh air. If shortness of breath occurs, support respiration and consult a physician.
Skin Contact	Remove contaminated clothing. Rinse contaminated skin immediately with plenty of water and soap and seek medical advice.
Eye Contact	Immediately rinse eyes thoroughly with running water as long as possible (approx. 15 min). Take injured quickly to factory medical center or call an ambulance (code word: eye accident).
Ingestion	Only as long as the patient is fully conscious: wash mouth and have the victim drink copious amounts of water (often vomiting will be induced). Consult a physician immediately or call for an ambulance and show label.

Self-protection of the first aider

For personal protection see Section 8

Acute/Chronic Effects and Symptoms	Irritating to skin. Eczemas (rare)
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Section 5: Fire fighting measures

Suitable Extinguishing Media	Water spray or fog, foam, dry chemical powder, CO2, dry sand
Unsuitable Extinguishing Media	No restrictions
Protective equipment for firefighters	Wear self-contained breathing apparatus and fire protective suite.
Additional Information for firefighters	Wear heavy protective equipment while firefighting. Do not allow run-off fire fighting to enter drains or water courses.

Section 6: Accidental release measures

Personal precautions	Avoid contact with skin, eyes and clothing.
Environmental precautions	Must not be released into sewers, drains or wells.
Methods for cleaning	Transfer large quantities into a container, rinse the rest with plenty of water.
Accidental Release	Take up with absorbent material. Prevent material from releasing into waste process water, non-contact cooling water, surface water, and soil. When clearing up spilt material avoid breathing dust, and skin contact. Before the clear up dampen solid waste or preferably use a permitted industrial vacuum cleaner. Label waste containers adequately. During the clear up and disposal wear suitable overalls, rubber gloves and if the need arises also effective respiratory protection.

For personal protection see Section 8, for disposal considerations see Section 13

Section 7: Handling and storage

Storage and Handling Precautions	Keep container tightly closed. Ensure efficient exhaust ventilation when using this product
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For Industrial Hygiene Measures see Section 8, Exposure controls / Personal protection

Conditions of storage	Protect against humidity, Protect against light, Protect against heat
Do not store together with	strong acids, bases, carbonates

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Maximum Storage Temperature (safety) <= 25 °C

Section 8: Exposure controls / Personal protection

Control parameters

List type	Value	Unit	
Internal exposure limit	140	µg/m3	HHA Database

Exposure Controls

Industrial Hygiene After finishing work wash hands and face with water and soap

Open Handling

Respiration	: Full face mask (EN136)
Filter	: P3 (EN143)
Eye	: Safety glasses (EN166)
Hand	: Butyl rubber gloves (EN374)
Additional protection	: working clothes (EN 340)

These values are derived from experiments, literature and information from the glove manufacturer.

They can also be derived from similar materials. In daily work please be aware that the using time depends on several factors and can be shorter than the officially tested permeation time.

Section 9: Physical and chemical properties

Formulation	powder
Physical state	solid
Colour	white
Odour	characteristic, faintly
Odour threshold	no data available
pH	= 3.5 - 5.5 (Concentration: = 4 %(m/V))
Melting point/range	218 - 237 °C
Boiling Point	no data available
Flash Point	not applicable
Evaporation Rate (Ref: Ether)	not applicable
Combustibility Test	Standard conditions: 1 = does not ignite (Temperature: 100 °C) Standard conditions: 1 = does not ignite (Temperature: 20 °C)
Explosion Limits	not applicable
Vapour Pressure [hPa]	not applicable
Vapour Density	not applicable
Density	no data available
Solubility (Aqueous Solvents)	Water: freely soluble
Solubility (Solvents)	ethyl alcohol: practically insoluble Acetone: practically insoluble chloroform: practically insoluble
Partition Coefficient	no data available
Autoignition/MIT	Temperature: = 490 °C Method: BAM MINIMUM IGNITION TEMPERATURE (DUST CLOUD)
Dynamic Decomposition	no data available
Isoperibolic Decomposition (>8h)	Stable up to: = 220 °C Method: Lütolf, open cup, as is (Temp.progr. 2.5°C/min, examined up to 350°C)

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	Exothermal decomposition may occur with delay (autocatalysis)
	Stable up to: = 200 °C
	Method: Grewer test method, air stream, as is (temp.progr. 1,2°C/min, examined up to 350°C)
	Stable up to: = 170 °C
	Method: long duration test open cup (8h)
Gas Formation	> 350 °C
Flammable Gases over	Temperature: = 350 °C (Gas volume: = 10 l/kg)
	Method: SANDOZ internal method
Viscosity	not applicable
Explosivity/Reactivity	Deflagration: No suspect of deflagration based on thermal data
	Negative
	Method: Falling hammer test
Test for self-heating	no data available
Fire-promoting properties	no data available
Other information	
Dust Explosion	Negative Minimum Ignition Energy: =
	Method: modified Hartmann tube
Specific Resistivity	= 2.7 - 3.7 * 10E10 Ohm m

Section 10: Stability and reactivity

Possibility of hazardous reactions

Materials to avoid None, when used and handled as intended.

Conditions to avoid

Conditions to avoid moisture
heating
ignition
light

Hazardous Decomposition Products

Hazardous Decomposition Products carbon monoxide
Carbon dioxide
nitrogen oxides
sulfur oxides

Section 11: Toxicological information

Acute Toxicity LD50: > 5000 mg/kg
Route: oral
Species: rat
LD50: > 5000 mg/kg
Route: oral
Species: mouse

Irritation, Corrosion Skin Potentially irritant

Sensitisation no data available

Mutagenicity no data available

Toxicological Hazard Classification

Acute Toxicity (oral): Cat.4
Acute Toxicity (dermal): Cat.4
Acute Toxicity Cat.4

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(inhalation):

Eye Corrosion / not classifiable

Irritation:

Skin Corrosion / not classifiable

Irritation:

Respiratory sensitizer not classifiable

Skin sensitizer: not classifiable

Germ cell mutation: not classifiable

Carcinogenicity: not classifiable

Reproductive toxicity: not classifiable

Specific organ toxicity not classifiable

(single dose), not lethal:

Specific organ toxicity not classifiable

(repeated exposure):

Aspiration Hazard: not applicable

Carcinogenicity listing

Public Lists International Lists: Not Listed

(International)

Section 12: Ecological information

Fish acute toxicity unknown

Aquatic invertebrate no data available

acute toxicity

Algae Toxicity no data available

Bacterial Respiration no data available

Inhibition

Biological Elimination Degradation: unknown

Partition Coefficient no data available

Biological no data available

accumulation

Soil and Sludge no data available

Sorption/Desorption

PBT assessment no data available

Other adverse effects no data available

Section 13: Disposal considerations

Disposal Requirements May be incinerated if local official regulations are observed.

Container Disposal For disposal local regulation is binding.

Section 14: Transport information

Regulation	DOT-Code:	IMDG-Code:	ICAO/IATA-DGR:
UN Number	0	0	0
UN Proper Shipping Name	-	-	-
Transport Hazard Class(es)			
Transport Label(s)			
Packing group			
Environmental Hazard			

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Additional Information

Special Precaution for User

Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Temperature Undefined

Conditions for

Transport

Section 15: Regulatory information

List type	Comment
according to annex I, EC Directive No. 67/548:	

Toxic Substances Control Act Not listed or exempted

Section 16: Other information

Abbreviations used

Recipient

Product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with legal regulations. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should therefore not be construed as guaranteeing specific properties.