

Gentamicin Solution (10 mg/ml)

According to Regulation (EC) No. 1907/2006 (REACH)

 Date of compilation
 04.10.2017

 Revision Date
 21.07.2023

 Version
 002/07.2023

Replaces version of 04.10.2017 (Version 001/10.2017)

Section 1 Identification of the substance/mixture and of the

company/undertaking

Product identifiers

Product name: Gentamicin Solution (10 mg/ml)

Catalogue No.: GEN-10B

REACH No.: A registration number is not available for this substance as the substance or its uses

are exempted from registration, the annual tonnage does not require a registration,

or the registration is envisaged for a later registration deadline.

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

Identified uses: Laboratory chemicals, Manufacture of substances

For research and development or in-vitro diagnostic use only. Not for therapeutic use. Not for use on human subjects.

Details of the supplier of the safety data sheet

Company: Capricorn Scientific GmbH

Auf der Lette 13 A 35085 Ebsdorfergrund

Germany

Phone: +49 6424 94464 0

E-Mail: <u>info@capricorn-scientific.com</u>
Website: <u>www.capricorn-scientific.com</u>

Emergency telephone number

Emergency Phone: +49 6424 94464 0 (on workdays, Mon. to Fri. from 8:00 – 16:00 h CET/CEST)

Section 2 Hazards identification

Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Respiratory sensitization (Category 1), H334 Skin sensitization (Category 1), H317



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Label elements

Labelling according to Regulation (EC) No 1272/2008

Classification of this product has been carried out in accordance with CLP Regulation (EC) No 1272/2008.

Pictogram



Signal Word Danger

Hazard statements:

H317 May cause an allergic skin reaction.

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

Precautionary statements:

P261 Avoid breathing mist or vapors.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.P284 Wear respiratory protection.

P302 IF ON SKIN: Wash with plenty of water.

+ P352

P333 If skin irritation or rash occurs: Get medical advice/ attention.

+ P313

Supplemental Hazard Statements none

Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.



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Section 3

Composition/information on ingredients

Substances

not relevant (mixture)

Mixtures

Synonyms:

Garamycin, Gentiomycin C

Identification		Chemical name/Classification		Concentration
CAS: 1405- EC: 215-7		Gentamicin Sulphate Salt		
Index: Non- REACH: Non-	applicable applicable	Resp. Sens. 1: H334 Skin Sens. 1: H317	Danger &	≥ 1 − <10 %

A registration number is not available for this substance as the substance, or its use, are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration, or the registration is envisaged for a later registration deadline.

For the full text of the H-Statements mentioned in this Section, see Section 2.

Section 4 First aid measures

Description of first aid measures

General notes/ Self-protection of the first aider

First aiders need to protect themselves. Show this material safety data sheet to the doctor in attendance.

Following eye contact

After eye contact: rinse out with plenty of water. Remove contact lenses.

Following skin contact

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower. Consult a physician.

Following ingestion

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

Following inhalation

After inhalation: fresh air. Call in physician.

Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2) and/or in section 11.



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Indication of any immediate medical attention and special treatment needed

No data available

Section 5

Firefighting measures

Extinguishing media

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given.

Special hazards arising from the substance or mixture

Nature of decomposition products not known. Not combustible. Ambient fire may liberate hazardous vapours.

Advice for firefighters

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

Further information

Prevent fire extinguishing water from contaminating surface water or the ground water system.

Section 6

Accidental release measures

Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Do not breathe vapors, aerosols. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert. For personal protection see section 8.

Environmental precautions

Do not let product enter drains.

Methods and material for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up carefully with liquid-absorbent material (e.g. Chemizorb®). Dispose of properly. Clean up affected area.

Reference to other sections

For disposal see section 13.



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Section 7 Handling and storage

Precautions for safe handling

Work under hood. Do not inhale substance/mixture. Avoid generation of vapours/aerosols. Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance. For precautions see section 2.

Conditions for safe storage, including any incompatibilities

Storage conditions

Tightly closed. Keep locked up or in an area accessible only to qualified or authorized persons.

Storage stability

Recommended storage temperature: +2°C to +8°C

Storage class

Storage class (TRGS 510): 12: Non-Combustible Liquids

Specific end uses

Apart from the uses mentioned in section 1 no other specific uses are stipulated.

Section 8 Exposure controls/personal protection

Control parameters

Ingredients with workplace control parameters

Exposure controls

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper removal technique (without touching glove's outer surface) to avoid with this product. Dispose of contaminated gloves after use in accordance applicable laws and good laboratory practices. Wash and dry hands

Selected protective gloves must satisfy the specifications of Regulation 2016/425 and the standard EN 374 derived from it.



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Full contact

Material: Nitrile rubber Minimum layer thickness: 0,11 mm

Break through time: 480 min Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile rubber Minimum layer thickness: 0,11 mm

Break through time: 480 min Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de, test method: EN374 If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the EC approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection

protective clothing

Respiratory protection

required when vapours/aerosols are generated.

Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system.

Recommended Filter type: Filter type ABEK

The entrepeneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures must be properly documented.

Control of environmental exposure

Do not let product enter drains.

Section 9

На

Physical and chemical properties

No data available

Information on basic physical and chemical properties

Physical state liquid No data available Color No data available Odor No data available Melting point/freezing point No data available Initial boiling point and boiling range Flammability (solid; gas) No data available Upper/lower flammability or explosive limits No data available No data available Flash point Autoignition temperature Not applicable No data available Decomposition temperature



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kinematic Viscosity

dynamic Viscosity

No data available

No data available

Water solubility at 20 °C soluble

Partition coefficient: n-octanol/water No data available Vapor pressure No data available Density No data available Relative density No data available Relative vapor density No data available Particle characteristics No data available

Explosive properties Not classified as explosive

Oxidizing properties none

Other information

No data available

Section 10 Stability and Reactivity

Reactivity

No data available

Chemical stability

The product is chemically stable under standard ambient conditions (room temperature).

Possibility of hazardous reactions

Violent reactions possible with: The generally known reaction partners of water.

Conditions to avoid

No information available

Incompatible materials

strong oxidizing agents

Hazardous decomposition products

In the event of fire: see section ${\bf 5}$



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Section 11 Toxicological information

Information on toxicological effects

Mixture

Acute toxicity

Oral: No data available Inhalation: No data available Dermal: No data available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitisation

Mixture may cause allergy or asthma symptoms or breathing difficulties if inhaled. Mixture may cause an allergic skin reaction.

Germ cell mutagenicity

No data available

Carcinogenicity

No data available

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

Endocrine disrupting properties

Product:

Assessment: The substance/mixture does not contain components considered to have endocrine

disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.



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To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. Hazardous properties cannot be excluded but are unlikely when the product is handled appropriately.

Components:

Gentamicin Sulphate

Acute toxicity

LD50 Oral - Rat - > 5.000 mg/kg Remarks: (RTECS) Inhalation: No data available Dermal: No data available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitization

May cause allergic respiratory and skin reactions

Germ cell mutagenicity

No data available

Carcinogenicity

No data available

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

Information on other hazards

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. Hazardous properties cannot be excluded but are unlikely when the product is handled appropriately.



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Section 12

Ecological information

Toxicity

Mixture

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Endocrine disrupting properties

Product:

Assessment: Substance/mixture does not contain components considered to have endocrine dis

rupting properties according to REACH Article 57(f) or Commission Delegated regula tion (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Other adverse effects

No data available

Components:

Gentamicin Sulphate

No data available

General comments on entries in Section 12 as a whole

Not described



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Section 13

Disposal considerations

Waste treatment methods

Product

The generation of waste should be avoided or minimized wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in according to approved disposal technique. Disposal of this product, its solutions or of any by-products, shall comply with the requirements of all applicable local, regional or national/federal regulations.

Section 14

Transport Information

In accordance with ADR / RID / IMDG / IATA

ADR/RID	IMDG	IATA			
UN number					
-	-	-			
UN proper shipping name					
Not dangerous goods	Not dangerous goods	Not dangerous goods			
Transport hazard classes					
-	-	-			
Packaging group					
-	-	-			
Environmental hazards					
no	Marine pollutant: no	no			

Special precautions for user

Further information

Not classified as dangerous in the meaning of transport regulations.



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Section 15 Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

Other regulations

Take note of Dir 94/33/EC on the protection of young people at work.

Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

Section 16 Other information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product regarding appropriate safety precautions. It does not represent any guarantee of the properties of the product.