

# Safety data sheet

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



## Gentamycin sulphate solution CELLPURE® 50 mg/ml sterile

article number: **HN09**  
Version: **2.0 en**  
Replaces version of: 2021-04-12  
Version: (1)

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Revision: 2022-08-10

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

### 1.1 Product identifier

Identification of the substance **Gentamycin sulphate solution CELLPURE® 50 mg/ml sterile**  
Article number **HN09**

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

Relevant identified uses: Laboratory chemical  
Laboratory and analytical use  
Uses advised against: Do not use for products which come into contact with foodstuffs. Do not use for private purposes (household).

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

Carl Roth GmbH + Co KG  
Schoemperlenstr. 3-5  
D-76185 Karlsruhe  
Germany

**Telephone:**+49 (0) 721 - 56 06 0  
**Telefax:** +49 (0) 721 - 56 06 149  
**e-mail:** sicherheit@carlroth.de  
**Website:** www.carlroth.de

Competent person responsible for the safety data sheet: :Department Health, Safety and Environment

**e-mail (competent person):** **sicherheit@carlroth.de**

### 1.4 Emergency telephone number

Name	Street	Postal code/city	Telephone	Website
National Poisons Information Service City Hospital	Dudley Rd	B187QH Birmingham	844 892 0111	

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

#### Classification acc. to GHS

Section	Hazard class	Cat-egory	Hazard class and category	Hazard statement
3.4R	Respiratory sensitisation	1	Resp. Sens. 1	H334
3.4S	Skin sensitisation	1	Skin Sens. 1	H317

For full text of abbreviations: see SECTION 16

### 2.2 Label elements

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### Labelling

#### Signal word

Danger

#### Pictograms

GHS08



#### Hazard statements

H317

May cause an allergic skin reaction

H334

May cause allergy or asthma symptoms or breathing difficulties if inhaled

#### Precautionary statements

##### Precautionary statements - prevention

P261

Avoid breathing mist/vapours

P280

Wear protective gloves/eye protection

##### Precautionary statements - response

P302+P352

IF ON SKIN: Wash with plenty of water

#### Hazardous ingredients for labelling:

Gentamycin sulphate

### 2.3 Other hazards

#### Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

not relevant (mixture)

Molecular formula

$C_{19-21}H_{39-43}N_5O_7 \cdot 2,5 H_2SO_4$

Molar mass

694,8 – 723,8 g/mol

### 3.2 Mixtures

#### Description of the mixture

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
Gentamycin sulphate	CAS No 1405-41-0  EC No 215-778-9	5	Resp. Sens. 1 / H334 Skin Sens. 1 / H317		

For full text of abbreviations: see SECTION 16

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## SECTION 4: First aid measures

### 4.1 Description of first aid measures



#### General notes

Take off contaminated clothing.

#### Following inhalation

Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.

#### Following skin contact

After contact with skin, wash immediately with plenty of water. In case of skin reactions, consult a physician.

#### Following eye contact

Rinse cautiously with water for several minutes. In all cases of doubt, or when symptoms persist, seek medical advice.

#### Following ingestion

Rinse mouth. Call a doctor if you feel unwell.

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

Allergic reactions, Cough, Dyspnoea

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

none

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media



#### Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings  
water spray, alcohol resistant foam, dry extinguishing powder, BC-powder, carbon dioxide (CO<sub>2</sub>)

#### Unsuitable extinguishing media

water jet

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

Ingredients of the mixture combustible. The product itself does not burn.

#### Hazardous combustion products

In case of fire may be liberated: Nitrogen oxides (NO<sub>x</sub>), Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>), Sulphur oxides (SO<sub>x</sub>)

### 5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

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## SECTION 6: Accidental release measures

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



#### For non-emergency personnel

Wearing of suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. Do not breathe vapour/spray.

### 6.2 Environmental precautions

Keep away from drains, surface and ground water.

### 6.3 Methods and material for containment and cleaning up

#### Advice on how to contain a spill

Covering of drains.

#### Advice on how to clean up a spill

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

#### Other information relating to spills and releases

Place in appropriate containers for disposal.

### 6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Provision of sufficient ventilation.

#### Advice on general occupational hygiene

Wash hands before breaks and after work. Keep away from food, drink and animal feedingstuffs.

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

Keep in a cool place.

#### Incompatible substances or mixtures

Observe hints for combined storage.

#### Consideration of other advice:

#### Specific designs for storage rooms or vessels

Recommended storage temperature: 2 – 8 °C

### 7.3 Specific end use(s)

No information available.

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## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### National limit values

#### Occupational exposure limit values (Workplace Exposure Limits)

This information is not available.

### 8.2 Exposure controls

#### Individual protection measures (personal protective equipment)

##### Eye/face protection



Use safety goggle with side protection.

##### Skin protection



##### • hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. The times are approximate values from measurements at 22 °C and permanent contact. Increased temperatures due to heated substances, body heat etc. and a reduction of the effective layer thickness by stretching can lead to a considerable reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger / smaller layer thickness, the respective breakthrough time is doubled / halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

##### • type of material

NBR (Nitrile rubber)

##### • material thickness

>0,11 mm

##### • breakthrough times of the glove material

>480 minutes (permeation: level 6)

##### • other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended.

##### Respiratory protection



Respiratory protection necessary at: Aerosol or mist formation. Type: A (against organic gases and vapours with a boiling point of > 65 °C, colour code: Brown).

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### Environmental exposure controls

Keep away from drains, surface and ground water.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state	liquid
Colour	colourless - clear - light yellow
Odour	odourless
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	~100 °C
Flammability	non-combustible
Lower and upper explosion limit	not determined
Flash point	not determined
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	3,5 – 5,5 (20 °C)
Kinematic viscosity	not determined
<u>Solubility(ies)</u>	
Water solubility	miscible in any proportion
<u>Partition coefficient</u>	
Partition coefficient n-octanol/water (log value):	this information is not available
Vapour pressure	23 hPa at 20 °C
<u>Density and/or relative density</u>	
Density	~1 g/cm <sup>3</sup>
Relative vapour density	information on this property is not available
Particle characteristics	not relevant (liquid)
<u>Other safety parameters</u>	
Oxidising properties	none

### 9.2 Other information

Information with regard to physical hazard classes:	hazard classes acc. to GHS (physical hazards): not relevant
Other safety characteristics:	

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Miscibility

completely miscible with water

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity

This material is not reactive under normal ambient conditions.

#### 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

#### 10.3 Possibility of hazardous reactions

No known hazardous reactions.

#### 10.4 Conditions to avoid

Keep away from heat.

#### 10.5 Incompatible materials

There is no additional information.

#### 10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

### SECTION 11: Toxicological information

#### 11.1 Information on toxicological effects

Test data are not available for the complete mixture.

##### Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

##### Classification acc. to GHS

##### Acute toxicity

Shall not be classified as acutely toxic.

##### Acute toxicity of components of the mixture

Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Gentamycin sulphate	1405-41-0	oral	LD50	>5.000 mg/kg	rat

##### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

##### Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

##### Respiratory or skin sensitisation

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

##### Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

##### Carcinogenicity

Shall not be classified as carcinogenic.

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### Reproductive toxicity

Shall not be classified as a reproductive toxicant.

### Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

### Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

### Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

### Symptoms related to the physical, chemical and toxicological characteristics

#### • If swallowed

Data are not available.

#### • If in eyes

Data are not available.

#### • If inhaled

May produce an allergic reaction, cough, Dyspnoea

#### • If on skin

May produce an allergic reaction, pruritis, localised redness

#### • Other information

none

### 11.2 Endocrine disrupting properties

None of the ingredients are listed.

### 11.3 Information on other hazards

There is no additional information.

## SECTION 12: Ecological information

### 12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

### Biodegradation

Data are not available.

### 12.2 Process of degradability

Data are not available.

### 12.3 Bioaccumulative potential

Data are not available.

### 12.4 Mobility in soil

Data are not available.

### 12.5 Results of PBT and vPvB assessment

Data are not available.

### 12.6 Endocrine disrupting properties

None of the ingredients are listed.



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### 12.7 Other adverse effects

Data are not available.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods



This material and its container must be disposed of as hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.

#### Sewage disposal-relevant information

Do not empty into drains.

### 13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process. Waste catalogue ordinance (Germany).

### 13.3 Remarks

Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities. Please consider the relevant national or regional provisions.

## SECTION 14: Transport information

- |  |   |
|--|---|
| 14.1 UN number or ID number  | not subject to transport regulations                                  |
| 14.2 UN proper shipping name   | not assigned  |
| 14.3 Transport hazard class(es)  | none  |
| 14.4 Packing group   | not assigned  |
| 14.5 Environmental hazards   | non-environmentally hazardous acc. to the dangerous goods regulations |
| 14.6 Special precautions for user  | There is no additional information.                                   |
| 14.7 Maritime transport in bulk according to IMO instruments   | The cargo is not intended to be carried in bulk.                      |
| 14.8 <u>Information for each of the UN Model Regulations</u>   |   |
| <b>Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information</b> |   |
| Not subject to ADR, RID and ADN.   |   |
| <b>International Maritime Dangerous Goods Code (IMDG) - Additional information</b>                           |   |
| Not subject to IMDG.   |   |
| <b>International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information</b>                    |   |
| Not subject to ICAO-IATA.  |   |

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## SECTION 15: Regulatory information

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

#### Relevant provisions of the European Union (EU)

##### Seveso Directive

2012/18/EU (Seveso III)			
No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the application of lower and upper-tier requirements	Notes
	not assigned		

##### Deco-Paint Directive

VOC content	0 %
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##### Industrial Emissions Directive (IED)

VOC content	0 %
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##### Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

none of the ingredients are listed

##### Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

none of the ingredients are listed

##### Water Framework Directive (WFD)

none of the ingredients are listed

##### Regulation on the marketing and use of explosives precursors

none of the ingredients are listed

##### Regulation on drug precursors

none of the ingredients are listed

##### Regulation on substances that deplete the ozone layer (ODS)

none of the ingredients are listed

##### Regulation concerning the export and import of hazardous chemicals (PIC)

none of the ingredients are listed

##### Regulation on persistent organic pollutants (POP)

none of the ingredients are listed

##### National regulations(GB)

##### List of substances subject to authorisation (GB REACH, Annex 14) / SVHC - candidate list

none of the ingredients are listed

##### Restrictions according to GB REACH, Annex 17

none of the ingredients are listed

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### Dangerous substances with restrictions (GB REACH, Annex 17)

Name of substance	Name acc. to inventory	CAS No	No
Gentamycin sulphate solution	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC		3

### Other information

Directive 94/33/EC on the protection of young people at work. Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

### National inventories

Country	Inventory	Status
AU	AIIC	all ingredients are listed
CA	DSL	not all ingredients are listed
CN	IECSC	all ingredients are listed
EU	ECSI	all ingredients are listed
JP	CSCL-ENCS	all ingredients are listed
KR	KECI	all ingredients are listed
MX	INSQ	all ingredients are listed
NZ	NZIoC	all ingredients are listed
PH	PICCS	all ingredients are listed
TR	CICR	not all ingredients are listed
TW	TCSI	all ingredients are listed
US	TSCA	not all ingredients are listed

#### Legend

AIIC	Australian Inventory of Industrial Chemicals
CICR	Chemical Inventory and Control Regulation
CSCL-ENCS	List of Existing and New Chemical Substances (CSCL-ENCS)
DSL	Domestic Substances List (DSL)
ECSI	EC Substance Inventory (EINECS, ELINCS, NLP)
IECSC	Inventory of Existing Chemical Substances Produced or Imported in China
INSQ	National Inventory of Chemical Substances
KECI	Korea Existing Chemicals Inventory
NZIoC	New Zealand Inventory of Chemicals
PICCS	Philippine Inventory of Chemicals and Chemical Substances (PICCS)
TCSI	Taiwan Chemical Substance Inventory
TSCA	Toxic Substance Control Act

## 15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

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### SECTION 16: Other information

#### Indication of changes (revised safety data sheet)

Alignment to regulation:

Restructuring: section 9, section 14

Section	Former entry (text/value)	Actual entry (text/value)	Safety-relevant
2.1		Classification acc. to GHS: change in the listing (table)	yes
2.1	Remarks: For full text of Hazard- and EU Hazard-statements: see SECTION 16.		yes
2.2		Pictograms: change in the listing (table)	yes
2.2	Labelling of packages where the contents do not exceed 125 ml: Signal word: Danger		yes
2.2		Labelling of packages where the contents do not exceed 125 ml: change in the listing (table)	yes
2.2		Labelling of packages where the contents do not exceed 125 ml: change in the listing (table)	yes
2.2		Labelling of packages where the contents do not exceed 125 ml: change in the listing (table)	yes
2.2	contains: Gentamycin sulphate		yes
2.3	Other hazards: There is no additional information.	Other hazards	yes
2.3		Results of PBT and vPvB assessment: This mixture does not contain any substances that are assessed to be a PBT or a vPvB.	yes

#### Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
DGR	Dangerous Goods Regulations (see IATA/DGR)
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
GB REACH	The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019, SI 2019/758 (as amended)

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Abbr.	Descriptions of used abbreviations
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
Resp. Sens.	Respiratory sensitisation
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
Skin Sens.	Skin sensitisation
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

### Key literature references and sources for data

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

### Classification procedure

Physical and chemical properties. The classification is based on tested mixture. Health hazards. Environmental hazards. The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

### List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.

### Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.