

Safety Data Sheet

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)
Classification according to Regulation (EC) No. 1272/2008 [CLP]

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

Product identifier

Product code	15710049
Product name	GENTAMICIN (10MG/ML)
Unique Formula Identifier (UFI)	Not Applicable
Chemical Name	Not Applicable
REACH registration number	No registration number is given yet for this substance / substances in this mixture since the annual import quantity is less than one tonnage per annum or the transition period for its registration according to Article 23 of REACH has not yet expired.

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

Relevant identified uses	For research use only
Use Description Code	SU22 - Professional uses: Public domain (administration, education, entertainment, services, craftsmen), PROC15 - Use as laboratory reagent, PC21 - Laboratory chemicals, SU24 - Scientific research and development
Uses advised against	Not for consumer use.

Details of the supplier of the safety data sheet

Manufacturer / Supplier

LIFE TECHNOLOGIES EUROPE BV
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2665 NN BLEISWIJK
NETHERLANDS
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Emergency telephone number

Revision number 4
Product code 15710049

Revision date 28-Apr-2025
Product name GENTAMICIN (10MG/ML)

24 hour Emergency Response for Hazardous Materials Within the USA + Canada: 1-800-424-9300 and
[or Dangerous Goods] Incident. Spill, Leak, Fire, 1-703-527-3887
Exposure, or Accident. Call CHEMTREC Outside the USA + Canada: 1-703-741-5970

Country Specific Emergency Number (if available):

CHEMTREC Ireland (Dublin) +(353)-19014670 (Greeting Language: English and Irish)
CHEMTREC UK (London) +(44)-870-8200418 (Greeting Language: English)

Section 2: HAZARDS IDENTIFICATION

Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Physical hazards

Not Hazardous

Health hazards

Respiratory sensitiser	Category 1
Skin sensitiser	Category 1

Environmental hazards

Not Hazardous

Additional information

Not Applicable

Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictograms



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

Prevention

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

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

P284 - In case of inadequate ventilation wear respiratory protection

Revision number 4
Product code 15710049

Revision date 28-Apr-2025
Product name GENTAMICIN (10MG/ML)

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

Response

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

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

P362 + P364 - Take off contaminated clothing and wash it before reuse

P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing

Storage

Not Applicable

Disposal

P501 - Dispose of contents/ container to an approved waste disposal plant

Other hazards

This product does not contain any known or suspected endocrine disruptors.

Section 3: Composition/information on ingredients

Mixtures

We recommend handling all chemicals with caution.

Chemical Name	CAS No	EINECS-No.	Weight-%	REACH registration number	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Gentamicin, sulfate (salt)	1405-41-0	215-778-9	1-3	-	Skin Sens.1 - H317 Resp. Sens. 1 - H334

Chemical Name	Specific concentration limit (SCL)	M-Factor	Acute Toxicity Estimate
Gentamicin, sulfate (salt)	-	-	-

Revision number 4
Product code 15710049

Revision date 28-Apr-2025
Product name GENTAMICIN (10MG/ML)

Section 4: First aid measures

Description of first aid measures

Skin contact	Wash off immediately with plenty of water for at least 15 minutes. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Immediate medical attention is required.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Immediate medical attention is required.
Ingestion	Never give anything by mouth to an unconscious person. Do not induce vomiting without medical advice. Get medical attention if symptoms occur.
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. If symptoms persist, call a doctor.
Notes to Physician	Treat symptomatically.

Most important symptoms and effects, both acute and delayed

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

Indication of any immediate medical attention and special treatment needed

If skin irritation or rash occurs: Get medical advice/attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Wear protective gloves/protective clothing and eye/face protection.

Section 5: Firefighting measures

Extinguishing media

Suitable extinguishing media	Water spray. Carbon dioxide (CO ₂). Foam. Dry chemical.
Unsuitable extinguishing media	No information available.

Special hazards arising from the substance or mixture Not known

Hazardous Combustion Products	No known hazardous decomposition products.
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Advice for firefighters	Wear self-contained breathing apparatus and protective suit.
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Section 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation

Always wear recommended Personal Protective Equipment

Use personal protection equipment

See section 8 for more information

Environmental precautions

No special environmental precautions required. Avoid discharge into drains and waterways whenever possible.

Methods and material for containment and cleaning up

Soak up with inert absorbent material.

Reference to other sections

See section 8 for more information.

Section 7: Handling and storage

Precautions for safe handling

Always wear recommended Personal Protective Equipment. See section 8 for more information. Do not get in eyes, on skin, or on clothing. Do not ingest. If during normal use the material presents a respiratory hazard, use adequate ventilation and/or wear appropriate respirator.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Keep in a dry, cool and well-ventilated place. Keep in properly labelled containers. Store in accordance with local regulations.

Specific end use(s)

For research use only.

SECTION 8: Exposure controls/personal protection

Control parameters

Chemical Name	EU OEL (TWA)	EU OEL (STEL)	EU Skin Notation
Gentamicin, sulfate (salt) 1405-41-0	None	None	None

Chemical Name	Austria	Belgium (TWA)	Czech Republic
Gentamicin, sulfate (salt) 1405-41-0	None	None	None

Chemical Name	Denmark (TWA)	Finland OEL (TWA)	France OEL (VME)
Gentamicin, sulfate (salt) 1405-41-0	None	None	None

Chemical Name	Croatia	Latvia	Romania
Gentamicin, sulfate (salt) 1405-41-0	None	None	None

Chemical Name	Germany OEL (TWA)	Ireland (TWA)	Italy OEL (TWA)
Gentamicin, sulfate (salt) 1405-41-0	None	None	None

Chemical Name	Lithuania OEL (TWA)	Netherlands OEL (MAC)	Norway
Gentamicin, sulfate (salt) 1405-41-0	None	None	None

Chemical Name	Poland	Portugal	Spain OEL (TWA)
Gentamicin, sulfate (salt) 1405-41-0	None	None	None

Chemical Name	Sweden - Occupational Exposure Limits - TLVs (LLVs)	Switzerland	United Kingdom
Gentamicin, sulfate (salt) 1405-41-0	None	None	None

Derived No Effect Level (DNEL)

See table for values

Component	Acute effects local (Dermal)	Acute effects systemic (Dermal)	Chronic effects local (Dermal)	Chronic effects systemic (Dermal)
Gentamicin, sulfate (salt) 1405-41-0 (1-3)	None	None	None	None

Component	Acute effects local (Inhalation)	Acute effects systemic (Inhalation)	Chronic effects local (Inhalation)	Chronic effects systemic (Inhalation)
Gentamicin, sulfate (salt) 1405-41-0 (1-3)	None	None	None	None

Predicted No Effect Concentration (PNEC)

See table for values

Chemical Name	Fresh water sediment	Fresh water	Water Intermittent	Microorganisms in sewage treatment	Soil (Agriculture)
Gentamicin, sulfate (salt) 1405-41-0	None	None	None	None	None

Component	Marine water	Marine water	Marine water	Food chain	Air
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Revision number 4
Product code 15710049

Revision date 28-Apr-2025
Product name GENTAMICIN (10MG/ML)

		sediment	Intermittent		
Gentamicin, sulfate (salt) 1405-41-0 (1-3)	None	None	None	None	None

Engineering Measures Ensure adequate ventilation, especially in confined areas.

Exposure controls

Personal protection equipment

Respiratory protection In case of insufficient ventilation wear respirators and components tested and approved under appropriate government standards.

Hand protection Wear suitable gloves

Eye protection Tight sealing safety goggles.

Skin and Body Protection Wear laboratory coat for body protection.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls

No special environmental precautions required. Avoid discharge into drains and waterways whenever possible.

Section 9: Physical and chemical properties

Information on basic physical and chemical properties

Physical state	liquid	
Colour	No information available	
Odour	No data	
Molecular Weight	No data	
Melting point / melting range	°C No data	°F No data
Boiling point / boiling range	°C No data	°F No data
Flammability (solid, gas)	No data available	
Lower explosion limit	No data	
Upper explosion limit	No data	
Flash point	°C No data	°F No data
Autoignition Temperature	°C No data	°F No data
Decomposition temperature	°C No data	°F No data
pH	4-6	
Evaporation rate	No data	
Viscosity	No data	
Solubility	No data available	
Partition coefficient: n-octanol/water	No data available	
Vapour Pressure	No data	
Specific gravity	No data	
Relative density	No data	
Vapour density	No data	
Explosive properties	No data	
Oxidising properties	No data	
Particle characteristics	No data	

Other information

Information with regards to physical hazard classes

No information available

Other safety characteristics

No information available

Section 10: Stability and reactivity

Reactivity	None known.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	Hazardous reaction has not been reported.
Conditions to avoid	No information available.
Incompatible materials	No dangerous reaction known under conditions of normal use.
Hazardous decomposition products	No known hazardous decomposition products.

Section 11: Toxicological information

Information on hazard classes as defined in Regulation (EC) No 1272/2008

Product Information No acute toxicity information is available for this product

Acute Toxicity

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Gentamicin, sulfate (salt)	> 5 g/kg (Rat)	No data available	No data available

Principal Routes of Exposure

Skin corrosion/irritation Data are conclusive but insufficient for classification

Serious eye damage/irritation Data are conclusive but insufficient for classification

Respiratory or skin sensitisation May cause sensitisation by inhalation and skin contact

Specific target organ toxicity (STOT) – single exposure Data are conclusive but insufficient for classification

Specific target organ toxicity (STOT) – repeated exposure Data are conclusive but insufficient for classification

Carcinogenicity Data are conclusive but insufficient for classification

Germ cell mutagenicity Data are conclusive but insufficient for classification

Reproductive Toxicity Data are conclusive but insufficient for classification

Aspiration Hazard Data are conclusive but insufficient for classification

Information on other hazards

Endocrine disrupting properties This product does not contain any known or suspected endocrine disruptors.

Section 12: Ecological information

Toxicity

The environmental impact of this product has not been fully investigated.

Chemical Name	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates	Toxicity to fish	Microtox Data	log Pow
Gentamicin, sulfate (salt)	No data available	No data available	No data available	No data available	No data available

Persistence and degradability No information available.

Bioaccumulative potential No information available.

Mobility in soil No information available.

Results of PBT and vPvB assessment No information available.

Endocrine disrupting properties

This product does not contain any known or suspected endocrine disruptors

Other adverse effects

Persistent Organic Pollutant This product does not contain any known or suspected substance

Ozone depletion potential (ODP) This product does not contain any known or suspected substance

Section 13: Disposal considerations

Waste treatment methods

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 accordance with 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

IATA / ADR / DOT-US / IMDG

Not regulated in the meaning of transport regulations

UN number or ID number	Not Applicable
UN proper shipping name	Not Applicable
Transport hazard class(es)	Not Applicable
Packing group	Not Applicable

Revision number 4
Product code 15710049

Revision date 28-Apr-2025
Product name GENTAMICIN (10MG/ML)

Environmental hazards

Not Applicable

Special precautions for user

Not Applicable

Maritime transport in bulk according to IMO instruments

Not Applicable.

Section 15: Regulatory information**Safety, health and environmental regulations/legislation specific for the substance or mixture****Substances of Very High Concern**

None

Substance subject to authorisation per REACH Annex XIV

None

Restricted substances under EC 1907/2006, Annex XVII

None

Regulation (EC) No 649/2012 (Rotterdam Convention - export/import of dangerous chemicals)

None

Regulation (EU) No 2019/1021 (Stockholm Convention – persistent organic pollutants)

None

EU - Substances Depleting the Ozone layer (1005/2009)

None

German Water hazard classes (Wassergefährdungsklassen)

Not classified.

Other International Inventories

Chemical Name	EINECS (European Union)	ELINCS (European List of Notified Chemical Substances)	ENCS (Japan)	PICCS (Philippines)
Gentamicin, sulfate (salt)	Listed	-	Listed	Listed

Chemical Name	AICS (Australia)	South Korea	Canada (DSL)	NDSL
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Revision number 4
Product code 15710049

Revision date 28-Apr-2025
Product name GENTAMICIN (10MG/ML)

		(KECL)		
Gentamicin, sulfate (salt)	-	Listed	-	-

Chemical safety assessment

No Chemical safety assessment has been carried out.

Reason for revision	Update according to Commission Regulation EU No. 2020/878
Revision number	4
Revision date	28-Apr-2025

References

- ECHA: <http://echa.europa.eu/>
- TOXNET: <http://toxnet.nlm.nih.gov/>
- eChemPortal: <http://www.echemportal.org/>
- LOLI database: <https://www.chemadvisor.com/loli-database>

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Respiratory sensitiser	Category 1	Calculation method
Skin sensitiser	Category 1	Calculation method

Abbreviations and acronyms

TWA - Time-Weighted Average
OELs - Occupational Exposure Limits
STEL - Short Term Exposure Limit
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
KECL - Korean Existing and Evaluated Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances
NZIoC - New Zealand Inventory of Chemicals
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
CEPA - Canadian Environmental Protection Act
EPA - Environmental Protection Agency
OSHA - Occupational Safety and Health Administration of the US Department of Labour
IATA - International Air Transport Association
DOT - Department of Transportation
IMDG - International Maritime Dangerous Goods
ACGIH - American Conference of Governmental Industrial Hygienists
NIOSH - National Institute for Occupational Safety and Health
AIHA - American Industrial Hygiene Association
HMIS - Department of Defense Hazardous Materials Information System
NTP - National Toxicology Program
IARC - International Agency for Research on Cancer

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 COMMISSION REGULATION (EU) 2020/878 amending Annex II to Regulation (EC) No 1907/2006.

"The above information was acquired by diligent search and/or investigation and the recommendations are based on prudent application of professional judgment. The information shall not be taken as being all inclusive and is to be used only as a guide. All materials and mixtures may present unknown hazards and should be used with caution. Since the Company cannot control the actual methods, volumes, or conditions of use, the Company shall not be held liable for any damages or losses resulting from the handling or from contact with the product as described herein. THE INFORMATION IN THIS SDS DOES NOT CONSTITUTE A WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE"

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