

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

1.1. Product identifier

Product form	: Substance
Substance name	: Second International Standard for Gentamicin
Chemical name	: Gentamicin sulfate
EC-No.	: 215-778-9
CAS-No.	: 1405-41-0
Product code	: 202500694

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

Relevant identified uses

Use of the substance/mixture	: Scientific research and development Technical testing and analysis For professional use only
Function or use category	: Laboratory chemicals

Uses advised against

Restrictions on use	: Not for food, drug or home use
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1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe
7, Allée Kastner, CS30026
F 67081 Strasbourg
France
T +33(0)388412035, F +33(0)388412771
sds@edqm.eu, www.edqm.eu

1.4. Emergency telephone number

Emergency number	: +33(0)390215608
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Serious eye damage/eye irritation, Category 2	H319	
Respiratory sensitisation, Category 1	H334	
Skin sensitisation, Category 1	H317	
Reproductive toxicity, Category 1B	H360	
Specific target organ toxicity – Repeated exposure, Category 1	H372	
Hazardous to the aquatic environment – Acute Hazard, Category 1	H400	(M=100)
Hazardous to the aquatic environment – Chronic Hazard, Category 1	H410	(M=10)

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Very toxic to aquatic life with long lasting effects. May damage fertility or the unborn child. Causes serious eye irritation. May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Causes damage to organs through prolonged or repeated exposure.

Second International Standard for Gentamicin

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

2.2. Label elements

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

Hazard pictograms (CLP)



GHS08

GHS09

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H360 - May damage fertility or the unborn child.
H372 - Causes damage to organs (Auditory system, kidneys) through prolonged or repeated exposure.
H410 - Very toxic to aquatic life with long lasting effects.

Precautionary statements (CLP)

: P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P260 - Do not breathe dust/fume/gas/mist/vapours/spray.
P264 - Wash hands, forearms and face thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P273 - Avoid release to the environment.
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P284 - Wear respiratory protection.
P302+P352 - IF ON SKIN: Wash with plenty of water.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P314 - Get medical advice/attention if you feel unwell.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P391 - Collect spillage.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

Hazard pictograms (CLP)



GHS08

2.3. Other hazards

No additional information available

Second International Standard for Gentamicin

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Gentamicin sulfate	CAS-No.: 1405-41-0 EC-No.: 215-778-9	≤ 100	Eye Irrit. 2, H319 Resp. Sens. 1, H334 Skin Sens. 1, H317 Repr. 1B, H360 STOT RE 1, H372 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=10)

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If experiencing respiratory symptoms: Call a poison center or a doctor.
First-aid measures after skin contact	: Take off contaminated clothing. Gently wash with plenty of soap and water. If symptoms persist, call a physician.
First-aid measures after eye contact	: Rinse immediately and thoroughly, pulling the eyelids well away from the eye (15 minutes minimum). Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	: Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.

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

Symptoms/effects after inhalation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Symptoms/effects after skin contact	: May cause an allergic skin reaction.
Symptoms/effects after eye contact	: Causes serious eye irritation. Redness, pain.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.
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5.3. Advice for firefighters

Firefighting instructions	: Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

Second International Standard for Gentamicin

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with skin, eyes and clothing.

For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Absorb with an inert material and place in an appropriate waste disposal container.

Methods for cleaning up : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

6.4. Reference to other sections

See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : Do not expose pregnant or breastfeeding women.

Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.

Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.

Packaging materials : Keep in original containers.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

Personal protection equipment

Eye and face protection

Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

Second International Standard for Gentamicin

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Skin protection

Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

Respiratory protection

Respiratory protection:

In case of dust formation use respirator with filter: P3

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white. almost white.
Appearance	: Powder.
Odour	: Not available
Odour threshold	: Not available
Melting point	: 218 – 237 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: 3,5 – 5,5 (4% Aqueous solution)
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 100 – 1000 g/l
Partition coefficient n-octanol/water (Log Kow)	: < 4 (Data from similar product: Gentamicin)
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

Second International Standard for Gentamicin

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

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

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal) : Not classified (Lack of data)
Acute toxicity (inhalation) : Not classified (Lack of data)

Gentamicin sulfate (1405-41-0)

LD50 oral rat	> 5000 mg/kg (RTECS No LY2625000)
Skin corrosion/irritation	: Not classified (Lack of data) pH: 3,5 – 5,5 (4% Aqueous solution)
Serious eye damage/irritation	: Causes serious eye irritation. pH: 3,5 – 5,5 (4% Aqueous solution)
Respiratory or skin sensitisation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Lack of data)
Reproductive toxicity	: May damage fertility or the unborn child.
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: Causes damage to organs (Auditory system, kidneys) through prolonged or repeated exposure.
Aspiration hazard	: Not classified (Lack of data)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Very toxic to aquatic life.
Hazardous to the aquatic environment, long-term (chronic) : Very toxic to aquatic life with long lasting effects.

Gentamicin sulfate (1405-41-0)

EC50 - Crustacea [1]	86 mg/l (48 Hours, Daphnia magna (Water flea)) (OECD 202 method) (Data from similar product: Gentamicin)
EC50 - Crustacea [2]	30 mg/l (96 Hours, Americamysis bahia) (US-EPA OPPTS 850.1035 Method) (Data from similar product: Gentamicin)
EC50 72h - Algae [1]	0,01 mg/l (72 Hours, Pseudokirchneriella subcapitata (Green algae)) (OECD 201 method) (Data from similar product: Gentamicin)
NOEC chronic algae	0,0015 mg/l (72 Hours, Pseudokirchneriella subcapitata (Green algae)) (OECD 201 method) (Data from similar product: Gentamicin)

Second International Standard for Gentamicin

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

12.2. Persistence and degradability

Gentamicin sulfate (1405-41-0)

Persistence and degradability Not rapidly degradable

12.3. Bioaccumulative potential

Gentamicin sulfate (1405-41-0)

Partition coefficient n-octanol/water (Log Kow) < 4 (Data from similar product: Gentamicin)

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

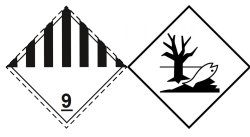
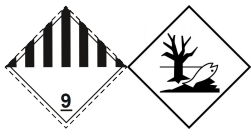
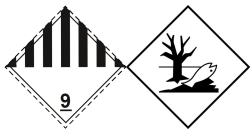
SECTION 13: Disposal considerations

13.1. Waste treatment methods

No additional information available

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
UN 3077	UN 3077	UN 3077
14.2. UN proper shipping name		
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	Environmentally hazardous substance, solid, n.o.s.
Transport document description		
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (-)	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT	UN 3077 Environmentally hazardous substance, solid, n.o.s., 9, III
14.3. Transport hazard class(es)		
9	9	9
		
14.4. Packing group		
III	III	III

Second International Standard for Gentamicin


Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

ADR	IMDG	IATA
14.5. Environmental hazards		
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes EmS-No. (Fire): F-A EmS-No. (Spillage): S-F	Dangerous for the environment: Yes
No supplementary information available		

14.6. Special precautions for user

Overland transport

Classification code (ADR)	: M7
Special provisions (ADR)	: 274, 335, 375, 601
Limited quantities (ADR)	: 5kg
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P002, IBC08, LP02, R001
Special packing provisions (ADR)	: PP12, B3
Mixed packing provisions (ADR)	: MP10
Portable tank and bulk container instructions (ADR)	: T1, BK1, BK2, BK3
Portable tank and bulk container special provisions (ADR)	: TP33
Tank code (ADR)	: SGAV, LGBV
Vehicle for tank carriage	: AT
Transport category (ADR)	: 3
Special provisions for carriage - Packages (ADR)	: V13
Special provisions for carriage - Bulk (ADR)	: VC1, VC2
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV13
Hazard identification number (Kemler No.)	: 90
Orange plates	: 
Tunnel restriction code (ADR)	: -

Transport by sea

Special provisions (IMDG)	: 274, 335, 375, 966, 967, 969
Limited quantities (IMDG)	: 5 kg
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: LP02, P002
Special packing provisions (IMDG)	: PP12
IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B3
Tank instructions (IMDG)	: BK1, BK2, BK3, T1
Tank special provisions (IMDG)	: TP33
Stowage category (IMDG)	: A
Stowage and handling (IMDG)	: SW23

Air transport

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y956
PCA limited quantity max net quantity (IATA)	: 30kgG
PCA packing instructions (IATA)	: 956
PCA max net quantity (IATA)	: 400kg
CAO packing instructions (IATA)	: 956
CAO max net quantity (IATA)	: 400kg
Special provisions (IATA)	: A97, A158, A179, A197, A215
ERG code (IATA)	: 9L

Second International Standard for Gentamicin

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

Explosives Precursors Regulation (EU 2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (EC 273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Full text of H- and EUH-statements:

Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H360	May damage fertility or the unborn child.
H372	Causes damage to organs (Auditory system, kidneys) through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Repr. 1B	Reproductive toxicity, Category 1B
Resp. Sens. 1	Respiratory sensitisation, Category 1
Skin Sens. 1	Skin sensitisation, Category 1
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1

Safety Data Sheet (SDS), EU

Second International Standard for Gentamicin

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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