

**Gentamicin Sulfate - 1405-41-0
P4020**



SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier:** Gentamicin, sulphate (salt)
CAS: 1405-41-0
EC: 215-778-9
Index: Non-applicable
REACH: Non-applicable
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant uses:
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:** Biowest SAS
Rue de la Caille
49340 Nuaillé - France
Phone.: 00 33 2 41 46 42 42 -
Fax: 00 33 2 41 46 40 50
biowest@biowest.net
www.biowest.net
- 1.4 Emergency telephone number:** ORFILA: 01 45 42 59 59

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture:**
Directive 67/548/EC and Directive 1999/45/EC:
This product was classified in accordance with Directive 67/548/EC and Directive 1999/45/EC, adapting the requirements to Regulation (EC) n°1907/2006 (REACH regulation).
Xn: R42/43 - May cause sensitisation by inhalation and skin contact
- CLP Regulation (EC) n° 1272/2008:**
Classification of this product has been carried out in accordance with CLP Regulation (EC) n° 1272/2008.
Resp. Sens. 1: Sensitisation, respiratory, Category 1, H334
Skin Sens. 1: Sensitisation, skin, Category 1, H317
- 2.2 Label elements:**
Directive 67/548/EC and Directive 1999/45/EC:
In accordance with the legislation, the elements on the label are as follows:
- Xn**
 Harmful
- R Phrases:**
R42/43: May cause sensitisation by inhalation and skin contact
- S Phrases:**
S2: Keep out of the reach of children
S22: Do not breathe dust
S24: Avoid contact with skin
S37: Wear suitable gloves
- Supplementary information:**
Non-applicable
- CLP Regulation (EC) n° 1272/2008:**
Danger
- Hazard statements:**

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SECTION 2: HAZARDS IDENTIFICATION (continue)

Resp. Sens. 1: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
Skin Sens. 1: H317 - May cause an allergic skin reaction

Precautionary statements:

P261: Avoid breathing dust/fume/gas/mist/vapours/spray
P272: Contaminated work clothing should not be allowed out of the workplace
P280: Wear protective gloves/protective clothing/eye protection/face 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
P333+P313: If skin irritation or rash occurs: Get medical advice/attention
P501: Dispose of contents and / or containers in accordance with regulations on hazardous waste or packaging and packaging waste respectively

2.3 Other hazards:

Non-applicable

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance:

Chemical description:

Components:

In accordance with Annex II of Regulation (EC) n°1907/2006 (point 3), the product contains:

Identification	Chemical name/Classification	Concentration
CAS: 1405-41-0 EC: 215-778-9 Index: Non-applicable REACH: Non-applicable	Gentamicin, sulphate (salt) Self-classified	75 - <100 %
	Directive 67/548/EC Xn: R42/43	
	Regulation 1272/2008 Resp. Sens. 1: H334; Skin Sens. 1: H317 - Danger	

To obtain more information on the risk of the substances consult sections 8, 11, 12 and 16.

3.2 Mixture:

Non-applicable

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

This product does not contain substances classified as dangerous for inhalation, however, in case of symptoms of intoxication remove the person affected from the exposure area and provide with fresh air. Seek medical attention if the symptoms get worse or persist.

By skin contact:

In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of modifications on the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Security Data Sheet

By eye contact:

This product does not contain substances classified as dangerous for eye contact. Rinse eyes thoroughly for at least 15 minutes with lukewarm water, ensuring that the person affected does not rub or close their eyes.

By ingestion/aspiration:

In case of consumption, seek immediate medical assistance showing the SDS of this product.

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

Acute and delayed effects are indicated in sections 2 and 11.

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

Non-applicable

SECTION 5: FIREFIGHTING MEASURES

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SECTION 5: FIREFIGHTING MEASURES (continue)

5.1 Extinguishing media:

Product is non-flammable under normal conditions of storage, manipulation and use. In the case of inflammation as a result of improper manipulation, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems. IT IS NOT RECOMMENDED to use tap water as an extinguishing agent.

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and individual respiratory equipment. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Destroy any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflammation, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

Isolate leaks provided that there is no additional risk for the people performing this task. Personal protection equipment must be used against potential contact with the spilled product (See section 8). Evacuate the area and keep out those who do not have protection.

6.2 Environmental precautions:

This product is not classified as dangerous to the environment. Keep product away from drains, surface and underground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- Precautions for safe manipulation

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B.- Technical recommendations for the prevention of fires and explosions

Product is non-flammable under normal conditions of storage, manipulation and use. It is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that can affect flammable products. Consult section 10 for information on conditions and materials that should be avoided.

C.- Technical recommendations to prevent ergonomic and toxicological risks

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Store in a cool, dry, well-ventilated location

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

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SECTION 7: HANDLING AND STORAGE (continue)

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the work environment

There are no environmental limits for the substances contained in the product

DNEL (Workers):

Non-applicable

DNEL (General population):

Non-applicable

PNEC:

Non-applicable



8.2 Exposure controls:

A.- General security and hygiene measures in the work place



As a preventative measure it is recommended to use basic Personal Protection Equipment, with the corresponding <<CE marking>> in accordance with Directive 89/686/EC. For more information on Personal Protection Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1.

All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.



B.- Respiratory protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory respiratory tract protection	Filter mask for gases and vapours		EN 405:2001+A1:2009	Replace when there is a taste or smell of the contaminant inside the face mask. If the contaminant comes with warnings it is recommended to use isolation equipment.



C.- Specific protection for the hands

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory hand protection	Chemical protective gloves		EN 374-1:2003 EN 374-3:2003/AC:2006 EN 420:2003+A1:2009	Replace the gloves at any sign of deterioration.

D.- Ocular and facial protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Panoramic glasses against liquid splash		EN 166:2001 EN 172:1994/A1:2000 EN 172:1994/A2:2001 EN ISO 4007:2012	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.

E.- Bodily protection



Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing		EN ISO 13688:2013	For professional use only.
	Anti-slip work shoes		EN ISO 20347:2012 EN ISO 20344:2011	None

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continue)

F.- Additional emergency measures

Emergency measure	Standards	Emergency measure	Standards
 Emergency shower	ANSI Z358-1 ISO 3864-1:2002	 Eyewash stations	DIN 12 899 ISO 3864-1:2002

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

V.O.C. (Supply):	0 % weight
V.O.C. density at 20 °C:	0 kg/m ³ (0 g/L)
Average carbon number:	Non-applicable
Average molecular weight:	Non-applicable

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C:	Not available
Appearance:	Not available
Color:	Not available
Odor:	Not available

Volatility:

Boiling point at atmospheric pressure:	Non-applicable *
Vapour pressure at 20 °C:	Non-applicable *
Vapour pressure at 50 °C:	Non-applicable *
Evaporation rate at 20 °C:	Non-applicable *

Product description:

Density at 20 °C:	Non-applicable *
Relative density at 20 °C:	Non-applicable *
Dynamic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 40 °C:	Non-applicable *
Concentration:	Non-applicable *
pH:	Non-applicable *
Vapour density at 20 °C:	Non-applicable *
Partition coefficient n-octanol/water 20 °C:	Non-applicable *
Solubility in water at 20 °C:	Non-applicable *
Solubility properties:	Non-applicable *
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	Non-applicable *

Flammability:

Flash Point:	Non Flammable (>60 °C)
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*Not relevant due to the nature of the product, not providing information property of its hazards.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continue)

Autoignition temperature:	Non-applicable *
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *

9.2 Other information:

Surface tension at 20 °C:	Non-applicable *
Refraction index:	Non-applicable *

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected if the following technical instructions storage of chemicals. See section 7.

10.2 Chemical stability:

Chemically stable under the conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

10.5 Incompatible materials:

Acids	Water	Combustive materials	Combustible materials	Others
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than recommended by the occupational exposure limits, it may result in adverse effects on health depending on the means of exposure:

A.- Ingestion:

- Acute toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for consumption. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

B- Inhalation:

- Acute toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

C- Contact with the skin and the eyes:

- Contact with the skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for skin contact. For more information see section 3.
- Contact with the eyes: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

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SECTION 11: TOXICOLOGICAL INFORMATION (continue)

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for the effects mentioned. For more information see section 3.
 - Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
 - Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- E- Sensitizing effects:
- Respiratory: Prolonged exposure can result in specific respiratory hypersensitivity.
 - Cutaneous: Prolonged contact with the skin can result in episodes of allergic contact dermatitis.
- F- Specific target organ toxicity (STOT)-time exposure:
Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- G- Specific target organ toxicity (STOT)-repeated exposure:
- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
 - Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- H- Aspiration hazard:
Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

Other information:

Non-applicable

Specific toxicology information on the substances:

Not available

SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

12.1 Toxicity:

Not available

12.2 Persistence and degradability:

Not available

12.3 Bioaccumulative potential:

Not available

12.4 Mobility in soil:

Not available

12.5 Results of PBT and vPvB assessment:

Non-applicable

12.6 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Code	Description	Waste class (Regulation (EU) No 1357/2014)
	It is not possible to assign a specific code, as it depends on the intended use by the user	Dangerous

Type of waste (Regulation (EU) No 1357/2014):

HP13 Sensitising

Waste management (disposal and evaluation):

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SECTION 13: DISPOSAL CONSIDERATIONS (continue)

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommended disposal down the drain. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) n°1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

Transport of dangerous goods by land:

With regard to ADR 2015 and RID 2015:

- 14.1 UN number:** Non-applicable
- 14.2 UN proper shipping name:** Non-applicable
- 14.3 Transport hazard class(es):** Non-applicable
Labels: Non-applicable
- 14.4 Packing group:** Non-applicable
- 14.5 Dangerous for the environment:** No
- 14.6 Special precautions for user**
Special regulations: Non-applicable
Tunnel restriction code: Non-applicable
Physico-Chemical properties: see section 9
Limited quantities: Non-applicable
- 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:** Non-applicable

Transport of dangerous goods by sea:

With regard to IMDG 37-14:

- 14.1 UN number:** Non-applicable
- 14.2 UN proper shipping name:** Non-applicable
- 14.3 Transport hazard class(es):** Non-applicable
Labels: Non-applicable
- 14.4 Packing group:** Non-applicable
- 14.5 Dangerous for the environment:** No
- 14.6 Special precautions for user**
Special regulations: Non-applicable
EmS Codes:
Physico-Chemical properties: see section 9
Limited quantities: Non-applicable
- 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:** Non-applicable

Transport of dangerous goods by air:

With regard to IATA/ICAO 2015:

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SECTION 14: TRANSPORT INFORMATION (continue)

14.1 UN number:	Non-applicable
14.2 UN proper shipping name:	Non-applicable
14.3 Transport hazard class(es):	Non-applicable
Labels:	Non-applicable
14.4 Packing group:	Non-applicable
14.5 Dangerous for the environment:	No
14.6 Special precautions for user	
Physico-Chemical properties:	see section 9
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:	Non-applicable

SECTION 15: REGULATORY INFORMATION

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

Candidate substances for authorisation under the Regulation (EC) 1907/2006 (REACH): Non-applicable

Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable

Regulation (EC) 1005/2009, about substances that deplete the ozone layer: Non-applicable

Active substances for which a decision of non-inclusion onto Annex I (Regulation (EU) No 528/2012): Non-applicable

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII, REACH):

Non-applicable

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as data used in a risk evaluation of the local circumstances in order to establish the necessary risk prevention measures for the manipulation, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) N° 1907/2006 (Regulation (EC) N° 453/2010)

Modifications related to the previous security card which concerns the ways of managing risks. :

Non-applicable

Texts of the legislative phrases mentioned in section 2.:

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

H317: May cause an allergic skin reaction

Texts of the legislative phrases mentioned in section 3.:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

Directive 67/548/EC and Directive 1999/45/EC:

R42/43: May cause sensitisation by inhalation and skin contact

CLP Regulation (EC) n° 1272/2008:

Resp. Sens. 1: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Skin Sens. 1: H317 - May cause an allergic skin reaction

Advice related to training:

Minimal training is recommended to prevent industrial risks for staff using this product, in order to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

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SECTION 16: OTHER INFORMATION (continue)

Principal bibliographical sources:

<http://esis.jrc.ec.europa.eu>
<http://echa.europa.eu>
<http://eur-lex.europa.eu>

Abbreviations and acronyms:

- ADR: European agreement concerning the international carriage of dangerous goods by road
- IMDG: International maritime dangerous goods code
- IATA: International Air Transport Association
- ICAO: International Civil Aviation Organisation
- COD: Chemical Oxygen Demand
- BOD5: 5-day biochemical oxygen demand
- BCF: Bioconcentration factor
- LD50: Lethal Dose 50
- CL50: Lethal Concentration 50
- EC50: Effective concentration 50
- Log-POW: Octanol–water partition coefficient
- Koc: Partition coefficient of organic carbon

The information contained in this security data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this security data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -