

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

GA-1000 GENTAMICIN SULFATE AMPHOTERICIN-B

Version 4.0

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Product name : GA-1000 GENTAMICIN SULFATE AMPHOTERICIN-B
Material number : CC-4083

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

Use of the Substance/Mixture : For research use only.
Recommended restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN OR ANIMAL IN VIVO OR DIAGNOSTIC USE.

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

E-mail address / Responsible/issuing person : sds@lonza.com

1.4 Emergency telephone number


Emergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Respiratory sensitisation, Category 1 H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitisation, Category 1 H317: May cause an allergic skin reaction.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

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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. P284 Wear respiratory protection. Response: 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. P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

Hazardous components which must be listed on the label:

Gentamicin, sulfate (salt)

2.3 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.

Ecological information: 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.

Toxicological information: 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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. REACH Registration Number	Classification	Concentration (% w/w)
Gentamicin, sulfate (salt)	1405-41-0 215-778-9	Resp. Sens. 1; H334 Skin Sens. 1; H317	>= 3 - < 5

For explanation of abbreviations see section 16.

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SECTION 4: First aid measures**4.1 Description of first aid measures**

- General advice : When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : Move to fresh air.
Call a physician immediately.
If breathing is irregular or stopped, administer artificial respiration.
- In case of skin contact : After contact with skin, wash immediately with plenty of soap and water.
Wash clothing before reuse.
Get medical attention if irritation develops and persists.
- In case of eye contact : In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
If eye irritation persists, consult a specialist.
- If swallowed : Immediately give plenty of water (if possible charcoal slurry).
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.
Take victim immediately to hospital.

4.2 Most important symptoms and effects, both acute and delayed

- Symptoms : Allergic appearance
sensitising effects

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically.
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SECTION 5: Firefighting measures**5.1 Extinguishing media**

- Suitable extinguishing media : Not combustible.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

5.2 Special hazards arising from the substance or mixture

- Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
- Further information : Use water spray to cool unopened containers.

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SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use respirator when performing operations involving potential exposure to vapour of the product.
Refer to protective measures listed in sections 7 and 8.

6.2 Environmental precautions

Environmental precautions : No special environmental precautions required.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Contain spillage, soak up with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and transfer to a container for disposal according to local / national regulations (see section 13).

6.4 Reference to other sections

For personal protection see section 8.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Advice on safe handling : In case of insufficient ventilation, wear suitable respiratory equipment.
Avoid exposure - obtain special instructions before use.
Use only in area provided with appropriate exhaust ventilation.
Avoid contact with skin and eyes.

Advice on protection against fire and explosion : Stable under normal conditions.

Hygiene measures : DANGER! Avoid contact with the skin and the eyes. Avoid breathing dust or spray mist. Wash hands before breaks and immediately after handling the product.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep frozen or refrigerated.

7.3 Specific end use(s)

Specific use(s) : No information available.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures

Avoid splashes.

Personal protective equipment

Eye protection	:	Safety glasses Safety goggles
Hand protection		
Material	:	Nitrile rubber
Rate of permeability	:	> 480 min
Skin and body protection	:	Choose body protection according to the amount and concentration of the dangerous substance at the work place. Complete suit protecting against chemicals
Respiratory protection	:	In case of mist, spray or aerosol exposure wear suitable personal respiratory protection and protective suit. Respirator with ABEK filter. Respirator with combination filter for vapour/particulate (EN 141)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Appearance	:	Aqueous solution
Colour	:	light yellow
Odour	:	odourless
Melting point/freezing point	:	0 °C
Initial boiling point and boiling range	:	No data available
Flammability	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available

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Flash point	:	Does not sustain combustion.
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Viscosity	:	No data available
Solubility(ies) Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available
Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	No data available
Particle characteristics	:	No data available

9.2 Other information

No data available

SECTION 10: Stability and reactivity**10.1 Reactivity**

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : No data available

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored normally.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity**

Acute oral toxicity : Remarks: No data available

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Aspiration toxicity

Remarks: No data available

11.2 Information on other hazards**Endocrine disrupting properties**

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.

Further informationRemarks: No data is available on the product itself.

SECTION 12: Ecological information**12.1 Toxicity**

Toxicity to fish : Remarks: No data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: No data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: No data available

12.5 Results of PBT and vPvB assessment

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.

12.6 Endocrine disrupting properties

Endocrine disrupting potential : 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.

12.7 Other adverse effects

Additional ecological information : No data available

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

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Product : Dispose of in accordance with local regulations.

Contaminated packaging : Dispose of as unused product.

SECTION 14: Transport information

IATA : Not dangerous goods

14.1 UN number : Not applicable

14.2 Proper shipping name : Not applicable

14.3 Transport hazard class(es) : Not applicable

14.4 Packing group : Not applicable

14.5 Environmental hazards : no

IMDG : Not dangerous goods

14.1 UN number : Not applicable

14.2 Proper shipping name : Not applicable

14.3 Transport hazard class(es) : Not applicable

14.4 Packing group : Not applicable

14.5 Environmental hazards : Marine pollutant: no

ADR : Not dangerous goods

14.1 UN number : Not applicable

14.2 Proper shipping name : Not applicable

14.3 Transport hazard class(es) : Not applicable

14.4 Packing group : Not applicable

14.5 Environmental hazards : no

RID : Not dangerous goods

14.1 UN number : Not applicable

14.2 Proper shipping name : Not applicable

14.3 Transport hazard class(es) : Not applicable

14.4 Packing group : Not applicable

14.5 Environmental hazards : no

DOT : Not dangerous goods

14.1 UN number : Not applicable

14.2 Proper shipping name : Not applicable

14.3 Transport hazard class(es) : Not applicable

14.4 Packing group : Not applicable

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TDG : Not dangerous goods

14.1 UN number : Not applicable

14.2 Proper shipping name : Not applicable

14.3 Transport hazard class(es) : Not applicable

14.4 Packing group : Not applicable

14.5 Environmental hazards : no

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Water hazard class (Germany) : WGK 1 slightly hazardous to water

15.2 Chemical safety assessment

not required

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SECTION 16: Other information

Classification of the mixture:		Classification procedure:
Resp. Sens. 1	H334	Calculation method
Skin Sens. 1	H317	Calculation method

Full text of H-Statements

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

Full text of other abbreviations

Resp. Sens.	:	Respiratory sensitisation
Skin Sens.	:	Skin sensitisation

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

Date format : dd.mm.yyyy

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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