

Antibiotic-Antimycotic 100X XC-A4110



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

1.1 Product identifier: Antibiotic-Antimycotic 100X – XC-A4110

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

Relevant uses: Used in biotechnology. For professional user/industrial user only. 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:

BIOSERA FRANCE SAS Rue de la Caille 49340 Nuaillé - France Phone : 00 33 5 61 97 69 69 Email : info@biosera.com www.biosera.com

1.4 Emergency telephone number: ORFILA: 01 45 42 59 59

SECTION 2: HAZARDS IDENTIFICATION **

2.1 Classification of the substance or mixture:

CLP Regulation (EC) no 1272/2008:

Classification of this product has been carried out in accordance with CLP Regulation (EC) no 1272/2008.

Acute Tox. 4: Acute toxicity if swallowed, Category 4, H302

Repr. 2: Reproductive toxicity, Category 2, H361

2.2 Label elements:

CLP Regulation (EC) no 1272/2008:

Warning





Hazard statements:

Acute Tox. 4: H302 - Harmful if swallowed

Repr. 2: H361 - Suspected of damaging fertility or the unborn child

Precautionary statements:

P201: Obtain special instructions before use

P202: Do not handle until all safety precautions have been read and understood

P264: Wash thoroughly after handling

P270: Do no eat, drink or smoke when using this product

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

P308+P313: IF exposed or concerned: Get medical advice/attention

P330: Rinse mouth

P501: Dispose of contents and / or containers in accordance with regulations on hazardous waste or packaging and packaging waste respectively

Supplementary information:

EUH208: Contains sodium [2S- $(2\alpha,5\alpha,6\beta)$]-3,3-dimethyl-7-oxo-6-(phenylacetamido)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate. May produce an allergic reaction

2.3 Other hazards:

Non-applicable

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance:

Non-applicable

3.2 Mixture:

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^{**} Changes with regards to the previous version



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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continued)

Chemical description: Mixture composed of additives and biocides

Components:

In accordance with Annex II of Regulation (EC) nº1907/2006 (point 3), the product contains:

Identification	C	nemical name/Classification	Concentration
	treptomycin sulphate	Self-classified	
EC: 223-286-0 Indexe Non-applicable REACH: Non-applicable Rue de la Caille	Regulation 1272/2008 Acute Tox. 4: H302; R	epr. 2: H361 - Warning	1 - <2,5 %
	odium 3§-(2α,5α,6β)]-3,3-dimethyl-7-oxo-6-(Self-classified ohenylacetamido)-4-thia-1-azabicyclo[3.2.0]he	
www.biosera.com	Regulation 1272/2008 Resp. Sens. 1: H334; \$	ikin Sens. 1: H317 - Danger	<1 %

To obtain more information on the risk of the substances consult sections 8, 11, 12, 15 and 16.

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 is not classified as hazardous through inhalation,however, it is recommended in case of intoxication symptoms to remove the person affected from the area of exposure, provide clean air and keep at rest. Request medical attention if symptoms persist.

By skin contact:

This product is not classified as hazardous when in contact with the skin. However, in case of skin contact it is recommended to remove contaminated clothes and shoes, rinse the skin or shower the person affected if necessary thoroughly with cold water and neutral soap. In case of serious reaction consult a doctor.

By eye contact:

Rinse eyes thoroughly with water for at least 15 minutes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, as this could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS of the product.

By ingestion/aspiration:

Request medical assistance immediately, showing the SDS of this product. Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. In the case of loss of consciousness do not administrate anything orally unless supervised by a doctor. Rinse out the mouth and throat, as they may have been affected during ingestion. Keep the person affected at rest.

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

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:

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SECTION 5: FIREFIGHTING MEASURES (continued)

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 spilt 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 hazardous 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:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

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

PREGNANT WOMEN SHOULD NOT BE EXPOSED TO THIS PRODUCT. Transfer in fixed places that comply with the necessary security conditions (emergency showers and eyewash stations in close proximity), using personal protection equipment, especially on the hands and face (See section 8). Limit manual transfers to containers of small amounts. 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):

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 occupational exposure limits for the substances contained in the product

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

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	CAT III	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

Pictogr	am	PPE	Labelling	CEN Standard	Remarks
Mandatory	hand	NON-disposable chemical protective gloves	CAT III	EN 374-1:2003 EN 374-3:2003/AC:2006 EN 420:2003+A1:2009	The Breakthrough Time indicated by the manufacturer must exceed the period during which the product is being used. Do not use protective creams after the product has come into contact with skin.

As the product is a mixture of several substances, the resistance of the glove material can not be calculated in advance with total reliability and has therefore to be checked prior to the application

D.- Ocular and facial protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
Mandatory face protection	Face mask	CAT II	EN 166:2001 EN 167:2001 EN 168:2001 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
Mandatory complete body protection	Disposable clothing for protection against chemical risks	CAT III	EN 13034:2005+A1:2009 EN 168:2001 EN ISO 13982-1:2004/A1:2010 EN ISO 6529:2001 EN ISO 6530:2005 EN 464:1994	For professional use only. Clean periodically according to the manufacturer's instructions.
Mandatory foot protection	Safety footwear for protection against chemical risk	CAT III	EN ISO 20345:2011 EN 13832-1:2006	Replace boots at any sign of deterioration.

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F.- Additional emergency measures



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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

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: $0 \text{ kg/m}^3 (0 \text{ g/L})$ Average carbon number: Non-applicable Average molecular weight: Non-applicable

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties: 9.1

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C: Liquid Fluid Appearance: Colour: Yellowish Odour: Odourless Odour threshold: Non-applicable *

Volatility:

Boiling point at atmospheric pressure: 100 °C 2350 Pa Vapour pressure at 20 °C:

Vapour pressure at 50 °C: 12381 Pa (12 kPa) Evaporation rate at 20 °C: Non-applicable *

Product description:

Density at 20 °C: 1037 kg/m³ 1,037 Relative density at 20 °C: Dynamic viscosity at 20 °C: 1,05 cP Kinematic viscosity at 20 °C: 1,01 cSt

Kinematic viscosity at 40 °C: Non-applicable * Concentration: Non-applicable *

7,5 - 9,5 pH:

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 * Explosive properties: Non-applicable * Oxidising properties: Non-applicable *

*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 (continued)

Flammability:

Flash Point: Non Flammable (>60 °C)

Flammability (solid, gas):

Autoignition temperature:

Lower flammability limit:

Upper flammability limit:

Non-applicable *

Non-applicable *

Non-applicable *

9.2 Other information:

Surface tension at 20 °C:

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 because the product is stable under recommended storage conditions. 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
Avoid strong acids	Not applicable	Not applicable	Not applicable	Avoid alkalis or strong bases

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 effect):
 - Acute toxicity: The consumption of a considerable dose can cause irritation in the throat, abdominal pain, nausea and vomiting.
 - 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 effect):
 - 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 (acute effect):

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

- 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):
 - 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: Suspected of damaging fertility or the unborn child
- E- Sensitizing effects:
 - Respiratory: Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous with sensitising effects. For more information see section 3.
 - Cutaneous: Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous with sensitising effects. For more information see section 3.
- F- Specific target organ toxicity (STOT) single 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:

Identification	Acu	Acute toxicity	
Streptomycin sulphate	LD50 oral	430 mg/kg	Rat
CAS: 3810-74-0	LD50 dermal	Non-applicable	
EC: 223-286-0	LC50 inhalation	Non-applicable	

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

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SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Code	Description	Waste class (Regulation (EU) No 1357/2014)
16 05 09	Discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08	Non dangerous

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

Non-applicable

Waste management (disposal and evaluation):

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) no1907/2006 (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 No.

environment:

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 Non-applicable

Annex II of Marpol and the

IBC Code:

Transport of dangerous goods by sea:

With regard to IMDG 38-16:

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 No

environment:

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 Non-applicable Annex II of Marpol and the

Transport of dangerous goods by air:

With regard to IATA/ICAO 2017:

IBC Code:

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SECTION 14: TRANSPORT INFORMATION (continued)

14.1UN number:Non-applicable14.2UN proper shipping name:Non-applicable14.3Transport hazard class(es):Non-applicableLabels:Non-applicable14.4Packing group:Non-applicable

14.5 Dangerous for the No

environment:

14.6 Special precautions for user

Physico-Chemical properties: see section 9 **14.7 Transport in bulk according to** Non-applicable

Annex II of Marpol and the

IBC Code:

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

Article 95, 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, etc):

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° 2015/830)

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:

CLP Regulation (EC) no 1272/2008 (SECTION 2, SECTION 16):

· Precautionary statements

Texts of the legislative phrases mentioned in section 2:

H302: Harmful if swallowed

 $\label{eq:H361: M361: Suspected of damaging fertility or the unborn child} \\$

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

CLP Regulation (EC) nº 1272/2008:

Acute Tox. 4: H302 - Harmful if swallowed

Repr. 2: H361 - Suspected of damaging fertility or the unborn child

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:

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SECTION 16: OTHER INFORMATION (continued)

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.

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 LC50: Lethal Concentration 50 EC50: Effective concentration 50

Log-POW: Octanol—water partition coefficient Koc: Partition coefficient of organic carbon

The information contained in this safety 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 safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET
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