

**Phoenix Scientific – Gentamicin Sulfate 50mg/ml- A1005**



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

- 1.1 Product identifier:** Gentamicin Sulfate 50 mg/ml -A1005  
**Other means of identification:**  
**UFI:** FH00-H0S6-3003-4GA9
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**  
Relevant uses: Used in biotechnology. For professional users/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:**  
Phoenix Scientific, Unipessoal LDA  
Rua Afonso de Almeida nº16, V11 8600-674 Lagos, Portugal  
Phone: +351308800210  
sales@phoenix-scientific.com  
www.phoenix-scientific.com
- 1.4 Emergency telephone number:** CIAV (Centro de Informação Antivenenos): +351 800 250 250

**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.

Resp. Sens. 1: Sensitisation, respiratory, Category 1, H334

Skin Sens. 1: Sensitisation, skin, Category 1, H317

**2.2 Label elements:**

**CLP Regulation (EC) No 1272/2008:**

**Danger**



**Hazard statements:**

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.

P280: Wear protective gloves/protective clothing/respiratory protection/eye protection/protective footwear.

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.

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.

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

**Substances that contribute to the classification**

Gentamicin, sulphate (salt) (CAS: 1405-41-0)

**UFI:** FH00-H0S6-3003-4GA9

**2.3 Other hazards:**

Product fails to meet PBT/vPvB criteria

Endocrine- disrupting properties: the product fails to meet criteria

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

**3.1 Substance:**

**Chemical description:** Mixture composed of additives and biocides

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**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

**Components:**

In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

Identification	Chemical name/ Classification	Concentration
Cas: 1405-41-0	<b>Gentamicin, sulphate (salt)</b> <sup>(1)</sup> Self-classified	2,5%-<10%
EC: 215-778-9		
Index: Non-applicable	Regulation 1272/2008 Resp. Sens. 1: H334; Skin Sens. 1: H317- Danger	
REACH: Non-applicable		

<sup>(1)</sup>Main Component

To obtain more information on the hazards of the substances consult sections 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:**

Remove the person affected from the area of exposure, provide with fresh air and keep at rest. In serious cases such as cardiorespiratory failure, artificial resuscitation techniques will be necessary (mouth to mouth resuscitation, cardiac massage, oxygen supply, etc.) requiring immediate medical assistance.

**By skin contact:**

May cause an allergic skin reaction. In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of changes on the skin (stinging, redness, rashes, blisters...), seek medical advice with this Safety Data Sheet

**By eye contact:**

Rinse eyes thoroughly with lukewarm water for at least 15 minutes. Do not allow the person affected to rub or close their eyes.

If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, in which case 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:**

In case of consumption, seek immediate medical assistance showing the SDS for the 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**

**5.1 Extinguishing media:**

**Suitable extinguishing media:**

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems.

**Unsuitable extinguishing media:**

Non-applicable

**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.

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**SECTION 5: FIREFIGHTING MEASURES**

**5.3 Advice for firefighters:**

Depending on the magnitude of the fire it may be necessary to use full protective clothing and self-contained breathing apparatus (SCBA). 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. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, 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:**

**For non-emergency personnel:**

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.

**For emergency responders:**

Wear protective equipment. Keep unprotected persons away. See section 8.

**6.2 Environmental precautions:**

This product is not classified as hazardous to the environment. Keep product away from drains, surface and ground 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.- General precautions for safe use

Comply with the current legislation concerning the prevention of industrial risks with regards manually handling weights. Maintain order, cleanliness and dispose of using safe methods (section 6).

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

Product is non-flammable under normal conditions of storage, handling 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 on general occupational hygiene

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

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**SECTION 7: HANDLING AND STORAGE**

**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 workplace (European OEL, not country-specific legislation): There is no applicable occupational exposure 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.- Individual protection measures, such as personal protective equipment**

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Regulation (EU) 2016/425. For more information on Personal Protective 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 labor 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 405:2002 + A1:2010	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	Protective gloves against minor risks			Replace gloves in case of any sign of damage. For prolonged periods of exposure to the product for professional users/industrials, we recommend using CE III gloves in line with standards EN ISO 21420:2020 and EN ISO 374-1:2016 + A1:2018

**D.- Eye and face protection**

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Panoramic glasses against splash/projections		EN 166:2002 EN ISO 4007:2018	Clean daily and disinfect periodically according to the manufacture's instructions. Use if there is a risk of splashing


**E.- Body protection**

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing			Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 6529:2013, EN ISO 6530:2005, EN ISO 13688:2013, EN 464:1994.



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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Anti-slip work shoes		EN ISO 20347:2012	Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 20345:2012 and EN ISO 13832-1:2007

F.- Additional emergency measures

Emergency Measure	Standards	Emergency Measure	Standard
 Emergency shower	ANSI Z358-1 ISO 3864-1:2011, ISO 3864-4:2011	 Eyewash stations	DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011

**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<sup>3</sup> (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: Liquid
- Appearance: Fluid
- Colour: Yellowish
- Odour: Odourless
- Odour threshold: Non-applicable\*

**Volatility:**

- Boiling point at atmospheric pressure: 100°C
- Vapour pressure at 20°C: 2350 Pa
- Vapour pressure at 50°C: 12381,01Pa (12,38 kPa)
- Evaporation rate at 20°C: Non-applicable\*

**Product description:**

- Density at 20°C: 1032 kg/m<sup>3</sup>
- Relative density at 20°C: 1,032
- Dynamic viscosity at 20°C: 1,03 cP
- Kinematic viscosity at 20°C: 0,99 mm<sup>2</sup>/s
- Kinematic viscosity at 40°C: Non-applicable\*
- Concentration: Non-applicable\*
- pH: 4-6
- 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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**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

Flammability (solid, gas):	Non-applicable*
Autoignition temperature:	Non-applicable*
Lower flammability limit:	Non-applicable*
Upper flammability limit:	Non-applicable*
<b>Particle characteristics:</b>	
Median equivalent diameter:	Non-applicable*

**9.2 Other information:**

**Information with regard to physical hazard classes:**

Explosive properties:	Non-applicable*
Oxidizing properties:	Non-applicable*
Corrosive to metals:	Non-applicable*
Heat of combustion:	Non-applicable*
Aerosols-total percentage (by mass) of flammable components:	Non-applicable*

**Other safety characteristics:**

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 because the product is stable under recommended storage conditions. See section 7.

**10.2 Chemical stability:**

Chemically stable under the indicated 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	Oxidizing 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 (CO<sub>2</sub>), carbon monoxide and other organic compounds

**SECTION 11: TOXICOLOGICAL INFORMATION**

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

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 the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

**A-Ingestion (acute effect):**

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

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**SECTION 11: TOXICOLOGICAL INFORMATION**

**C-Contact with the skin and the eyes (acute effect):**

- Contact with the skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous 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 hazardous 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 hazardous for the effects mentioned. For more information see section 3.

IARC: Non-applicable

- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous 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 hazardous for this effect. For more information see section 3.

**E-Sensitizing effects:**

- Respiratory: Prolonged exposure can result in specific respiratory hypersensitivity.
- Skin: Prolonged contact with the skin can result in episodes of allergic contact dermatitis.

**F-Specific target organ toxicity (STOT) - single exposure:**

Based on available data, the classification criteria are not met. However, it contains substances classified as hazardous for inhalation. 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 hazardous 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 hazardous 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 hazardous for this effect. For more information see section 3.

**Other information:**

Non-applicable

**Specific toxicology information on the substances:**

Non-applicable

**11.2 Information on other hazards:**

**Endocrine disrupting properties**

Endocrine-disrupting properties: The product fails to meet the criteria.

**Other information**

Non-applicable

**SECTION 12: ECOLOGICAL INFORMATION**

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

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

**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:**

Product fails to meet PBT/vPvB criteria

**12.6 Endocrine disrupting properties:**

Endocrine-disrupting properties: The product fails to meet the criteria.

**12.7 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.

Waste should not be disposed of to drains. See paragraph 6.2.

**Regulations related to waste management:**

In accordance with Annex II of Regulation (EC) No 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 (ADR 2023 and RID 2023)	By Sea (IMDG 40-20)	By Air (IATA/ICAO 2023)	
<b>UN number or ID Number</b>	Non-applicable	Non-applicable	Non-applicable	
<b>UN proper shipping name</b>	Non-applicable	Non-applicable	Non-applicable	
<b>Transport hazard</b>	<b>Class(es)</b>	Non-applicable	Non-applicable	
	<b>Labels</b>	Non-applicable	Non-applicable	
<b>Packing Group</b>	Non-applicable	Non-applicable	Non-applicable	
<b>Environmental hazards</b>	No	No	No	
<b>Special precautions for user</b>	<b>Special regulations</b>	Non-applicable	-	
	<b>Tunnel restriction code</b>	Non-applicable	-	
	<b>Physico-Chemical properties</b>	See section 9	See Section 9	See Section 9
	<b>Limited quantities</b>	Non-applicable	Non-applicable	-
<b>Maritime transport in bulk according to IMO instruments</b>	Non-applicable	Non-applicable	Non-applicable	

**SECTION 15: REGULATORY INFORMATION**

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

Candidate substances for authorization under the Regulation (EC) No 1907/2006 (REACH): Non-applicable

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

Regulation (EC) No 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

**Seveso III:** Non-applicable

**Limitations to commercialization and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc ....):**

Shall not be used in:

—ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,

—tricks and jokes,

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**SECTION 15: REGULATORY INFORMATION**

—games for one or more participants, or any article intended to be used as such, even with ornamental aspects.

**Specific provisions in terms of protecting people or the environment:**

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, 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:**

The SDS shall be supplied in an official language of the country where the product is placed on the market. This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (COMMISSION REGULATION (EU) 2020/878).

**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

**CLP Regulation (EC) No 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:**

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

**Principal bibliographical sources:**

<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 Organization

COD: Chemical Oxygen Demand

BOD5: 5day biochemical oxygen demand BCF: Bioconcentration factor

BCF: Bioconcentration factor

LD50: Lethal Dose 50

LC50: Lethal Concentration 50 EC50: Effective concentration 50

LogPOW: Octanolwater partition coefficient

Koc: Partition coefficient of organic carbon

UFI: unique formula identifier

IARC: International Agency for Research on Cancer

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.