Safety data sheet

According to COMMISSION REGULATION (EU) 2020/878

1379 - Tetracycline hydrochloride ≥95% RTECS: QI8750000



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

1.1 Product identifier: 1379 - Tetracycline hydrochloride ≥95%

RTECS: Q18750000
Tetracycline hydrochloride

CAS: 64-75-5
EC: 200-593-8
Index: Non-applicable

REACH: 01-2120083280-63-XXXX

Other means of identification:

Non-applicable

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

Relevant uses: Miscellaneous; raw material for product formulation; in vitro diagnostic; research use. For professional users 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:

GERBU Biotechnik GmbH 69123 Heidelberg - Germany Phone: +49 6221 7264167 safety@gerbu.de www.gerbu.de

1.4 Emergency telephone number:

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

Aquatic Chronic 4: Hazardous to the aquatic environment, long-term hazard, Category 4, H413

Lact.: Reproductive toxicity, effects on or via lactation, H362

Repr. 2: Reproductive toxicity, Category 2, H361 Skin Irrit. 2: Skin irritation, Category 2, H315

2.2 Label elements:

CLP Regulation (EC) No 1272/2008:

Warning





Hazard statements:

Aquatic Chronic 4: H413 - May cause long lasting harmful effects to aquatic life.

Lact.: H362 - May cause harm to breast-fed children.

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

Precautionary statements:

P201: Obtain special instructions before use.

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

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

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

2.3 Other hazards:

Product fails to meet PBT/vPvB criteria

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

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

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



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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continued)

3.1 Substance:

Chemical description: Chemical substance

Components:

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

Identification		Chemical name/Classification		Concentration
64-75-5 200-593-8 Non-applicable H: 01-2120083280-63- XXXX	Tetracycline hydrochlo	racycline hydrochloride Self-c		
	Regulation 1272/2008	Acute Tox. 4: H302; Aquatic Chronic 4: H413; Lact.: H362; Repr. 2: H361; Skin Irrit. 2: H315 - Warning	<u>(1)</u>	75 - <100 %

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

This product does not contain substances classified as hazardous 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:

Remove contaminated clothing and footwear, rinse skin or shower the person affected if appropriate with plenty of cold water and neutral soap. In serious cases see a doctor. If the product causes burns or freezing, clothing should not be removed as this could worsen the injury caused if it is stuck to the skin. If blisters form on the skin, these should never be burst as this will increase the risk of infection.

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:

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 administer 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:

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 (continued)

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:

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal

For emergency responders:

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

6.2 Environmental precautions:

Avoid at all cost any type of spillage into an aqueous medium. Contain the product absorbed appropriately in hermetically sealed containers. Notify the relevant authority in case of exposure to the general public or the environment.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal

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

Due to its non-inflammable nature, the product does not present a fire risk under normal conditions of storage, handling and

C.- Technical recommendations on general occupational hygiene

PREGNANT WOMEN SHOULD NOT BE EXPOSED TO THIS PRODUCT. Transfer in designated areas that comply with the necessary safety 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 small amounts only. Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

Preferably use aspiration for cleaning. Given the danger of the product by inhalation, any cleaning method that involves exposure to the product in this way (sweeping, etc.) is not recommended

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Minimum Temp.: 8 °C

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.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace:

Nuisance dust: Inhalable dust 10 mg/m3 // Respirable dust 4 mg/m3

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 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 405:2002+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	NON-disposable chemical protective gloves	CAT III	EN ISO 374-1:2016+A1:2018 EN 16523-1:2015+A1:2018 EN ISO 21420:2020	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.

D.- Eye and face protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
Mandatory face protection	Face shield	CATII	EN 166:2002 EN 167:2002 EN 168:2002 EN ISO 4007:2018	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.

E.- Body protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
Mandatorycom plete body protection	Disposable clothing for protection against chemical risks	CAT III	EN 13034:2005+A1:2009 EN 168:2002 EN ISO 13982- 1:2004/A1:2010 EN ISO 6529:2013 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 13832-1:2019	Replace boots at any sign of deterioration.

F.- Additional emergency measures



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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Emergency measure Standards Emergency measure Standards **O.**+ ANSI Z358-1 ISO 3864-1:2011, ISO 3864-4:2011 DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011 Emergency shower Eyewash stations

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/m3 (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:

Solid Physical state at 20 °C:

Appearance: Not available Colour: Not available Odour: Not available Odour threshold: Non-applicable *

Volatility:

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

Product description:

Density at 20 ºC: Non-applicable * Relative density at 20 ºC: Non-applicable * Dynamic viscosity at 20 ºC: Non-applicable * Kinematic viscosity at 20 ºC: Non-applicable * Kinematic viscosity at 40 ºC: 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 ºC: Non-applicable * Solubility properties: Non-applicable * Non-applicable * Decomposition temperature: Melting point/freezing point: Non-applicable *

Flammability:

Flash Point: 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 (solid, gas): Non-applicable * Autoignition temperature: Non-applicable * Lower flammability limit: Non-applicable * Upper flammability limit: Non-applicable *

Explosive (Solid):

Lower explosive limit: Non-applicable * Upper explosive limit: Non-applicable *

Particle characteristics:

Median equivalent diameter: Non-applicable *

Other information: 9.2

Information with regard to physical hazard classes:

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

components:

Other safety characteristics:

Surface tension at 20 ºC: 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
Notapplicable	Notapplicable	Notapplicable	Notapplicable	Notapplicable

10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Notapplicable	Notapplicable	Notapplicable	Avoid alkalis orstrong 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 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:

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

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: The consumption of a considerable dose can cause irritation in the throat, abdominal pain, nausea and vomiting.
- Corrosivity/Irritability: The consumption of a considerable dose can cause irritation in the throat, abdominal pain, nausea and vomiting.

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, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

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

- Contact with the skin: Produces skin inflammation.
- 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: Suspected of damaging fertility or the unborn child

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous with sensitising effects. 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.
- 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 hazardous 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 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:

Identification	Acute toxicity		Genus
Tetracycline hydrochloride	LD50 oral	500 mg/kg (ATEi)	
CAS: 64-75-5	LD50 dermal	Non-applicable	
EC: 200-593-8	LC50 inhalation	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

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SECTION 12: ECOLOGICAL INFORMATION (continued)

12.1 Toxicity:

Product-specific aquatic toxicity:

Acute toxicity		Species	Genus	
LC50	220 mg/L (96 h)	N/A	Algae	

Substance-specific aquatic 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

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

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

HP14 Ecotoxic, HP6 Acute Toxicity, HP10 Toxic for reproduction, HP4 Irritant - skin irritation and eye damage

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, The Waste Regulations 2011, 2011 No. 988). As under 15 01 (2014/955/EU) 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

This product is not regulated for transport (ADR/RID,IMDG,IATA)

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) No 1907/2006 (REACH): Non-applicable

Substances included in Annex XIV of REACH ("Authorisation 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

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SECTION 15: REGULATORY INFORMATION (continued)

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 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 Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (CDG 2009), SI 2009 No 1348

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (Amendment) Regulations 2011, 2011 No. 1885

Control of Substances Hazardous to Health Regulations 2002 (as amended)

EH40/2005 Workplace exposure limits

The Waste Regulations 2011, 2011 No. 988

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) No 1907/2006 (COMMISSION REGULATION (EU) 2020/878)

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

COMMISSION REGULATION (EU) 2020/878

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.

H315: Causes skin irritation.

H361: Suspected of damaging fertility or the unborn child.

H362: May cause harm to breast-fed children.

H413: May cause long lasting harmful effects to aquatic life.

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.

Aquatic Chronic 4: H413 - May cause long lasting harmful effects to aquatic life.

Lact.: H362 - May cause harm to breast-fed children.

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

Skin Irrit. 2: H315 - Causes skin irritation.

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

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Abbreviations and acronyms:

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SECTION 16: OTHER INFORMATION (continued)

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: 5day biochemical oxygen demand

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.

- END OF SAFETY DATA SHEET
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