



**BIOLABO SAS - Blo TT Thrombin Time - R1 12x2mL
REF13980**

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

- 1.1 Product identifier:** BIOLABO SAS - Blo TT Thrombin Time - R1 12x2mL
REF13980
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant uses: Chemical sample for use in laboratories. 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:**
BIOLABO SAS
Les Hautes Rives
02160 Maizy - France
Phone.: 0323251550 - Fax: 0323256256
info@biolabo.fr
www.biolabo.fr
- 1.4 Emergency telephone number:** BIOLABO (33) (0) 323251550 (08h00-18h00), ORFILA (33) (0)145 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. 2: Acute toxicity on contact with skin, Category 2, H310
Acute Tox. 3: Acute inhalation toxicity, Category 3, H331
Aquatic Chronic 3: Hazardous to the aquatic environment, long-term hazard, Category 3, H412
STOT RE 2: Specific target organ toxicity, repeated exposure, Category 2, H373
- 2.2 Label elements:**
CLP Regulation (EC) No 1272/2008:
Danger
-
- Hazard statements:**
Acute Tox. 2: H310 - Fatal in contact with skin
Acute Tox. 3: H331 - Toxic if inhaled
Aquatic Chronic 3: H412 - Harmful to aquatic life with long lasting effects
STOT RE 2: H373 - May cause damage to organs through prolonged or repeated exposure
- Precautionary statements:**
P264: Wash thoroughly after handling
P271: Use only outdoors or in a well-ventilated area
P280: Wear protective gloves/protective clothing/eye protection/face protection
P302+P352: IF ON SKIN: Wash with plenty of water
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing
P310: Immediately call a poison center/doctor
P403+P233: Store in a well-ventilated place. Keep container tightly closed
P501: Dispose of contents/container in accordance with regulations on hazardous waste or packaging and packaging waste respectively
- Substances that contribute to the classification**
Thiomersal
- 2.3 Other hazards:**
Product fails to meet PBT/vPvB criteria
RECONSTITUTED WORKING REAGENT (vial R1) IS NOT CLASSIFIED AS DANGEROUS ACCORDING TO 1272/2008 (CLP) REGULATION

** Changes with regards to the previous version

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1 Substance:**

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continued)



Non-applicable

3.2 Mixture:

Chemical description: Mixture of substances

Components:

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

Identification	Chemical name/Classification	Concentration
CAS: 10035-04-8 EC: Non-applicable Index: Non-applicable REACH01-2119494219-28- : XXXX	Calcium chloride · 2H₂O ^{□*} Self-classified	2,5 - <10 %
	Regulation 1272/2008 Eye Irrit. 2: H319 - Warning 	
CAS: 54-64-8 EC: 200-210-4 Index: 080-004-00-7 REACHNon-applicable :	Thiomersal ^{□*} ATP CLP00	<1 %
	Regulation 1272/2008 Acute Tox. 1: H310; Acute Tox. 2: H300+H330; Aquatic Acute 1: H400; Aquatic Chronic 1: H410; STOT RE 2: H373 - Danger 	

^{□*} Substances presenting a health or environmental hazard which meet criteria laid down in Regulation (EU) No. 2015/830

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

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

Request medical assistance immediately, 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:

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:

Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion.

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, 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. 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:

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SECTION 5: FIREFIGHTING MEASURES (continued)

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:

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

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.- 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

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

C.- Technical recommendations to prevent ergonomic and toxicological risks

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

D.- Technical recommendations to prevent environmental risks

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal See sections 8 and 13.

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 workplace

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

8.2 Exposure controls:

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

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



In accordance with the order of importance to control professional exposure (Directive 98/24/EC) it is recommended to use localized extraction in the work area as a collective protection measure to avoid exceeding the occupational exposure limits. In case of using personal protective equipment it should have CE marking in accordance with Directive 89/686/EC. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For additional information see subsection 7.1.

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

B.- Respiratory protection



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

C.- Specific protection for the hands





Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory hand protection	NON-disposable chemical protective gloves		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 predicted 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 shield		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.- Body protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory complete body protection	Disposable clothing for protection against chemical risks		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		EN ISO 20345:2011 EN 13832-1:2006	Replace boots at any sign of deterioration.

F.- Additional emergency measures

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

Environmental exposure controls:

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

*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)

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C:	Solid
Appearance:	Compact
Colour:	<input type="checkbox"/> White
Odour:	Not available
Odour threshold:	Non-applicable *

Volatility:

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

Product description:

Density at 20 °C:	Non-applicable *
Relative density at 20 °C:	Non-applicable *
Dynamic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 40 °C:	>20,5 cSt
Concentration:	Non-applicable *
pH:	Non-applicable *
Vapour density at 20 °C:	Non-applicable *
Partition coefficient n-octanol/water 20 °C:	Non-applicable *
Solubility in water at 20 °C:	Non-applicable *
Solubility properties:	Non-applicable *
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	Non-applicable *
Explosive properties:	Non-applicable *
Oxidising properties:	Non-applicable *

Flammability:

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

Explosive:

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

9.2 Other information:

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

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

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

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SECTION 10: STABILITY AND REACTIVITY (continued)

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	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Avoid direct impact	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 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, however, it contains substances classified as dangerous for consumption. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

B- Inhalation (acute effect):

- Acute toxicity : Inhalation after prolonged exposure may be lethal.
- 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):

- Contact with the skin: Can be fatal if the product is absorbed through the skin. For more information on the secondary effects of skin contact see section 2.
- Contact with the eyes: Based on available data, the classification criteria are not met. However, it does 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.
IARC: Non-applicable
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous with sensitising effects. For more information see section 3.
- Cutaneous: 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.

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

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

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: Exposure in high concentration can interfere with the central nervous system causing headache, dizziness, vertigo, nausea, vomiting, confusion, and in serious cases, loss of consciousness.
- 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	Acute toxicity		Genus
	LD50 oral	LD50 dermal	
Thiomersal CAS: 54-64-8 EC: 200-210-4	LD50 oral	75 mg/kg	Rat
	LD50 dermal	5 mg/kg (ATEi)	
	LC50 inhalation	0,05 mg/L (4 h) (ATEi)	
Calcium chloride · 2H2O CAS: 10035-04-8 EC: Non-applicable	LD50 oral	2031 mg/kg	Rat
	LD50 dermal	Non-applicable	
	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:

Identification	Acute toxicity		Species	Genus
	LC50	EC50		
Calcium chloride · 2H2O CAS: 10035-04-8 EC: Non-applicable	LC50	4630 mg/L (96 h)	Pimephales promelas	Fish
	EC50	2400 mg/L (48 h)	Daphnia magna	Crustacean
	EC50	Non-applicable		
Thiomersal CAS: 54-64-8 EC: 200-210-4	LC50	0.1 - 1 mg/L (96 h)		Fish
	EC50	0.1 - 1 mg/L		Crustacean
	EC50	0.1 - 1 mg/L		Algae

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 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Code	Description	Waste class (Regulation (EU) No 1357/2014)
16 05 06*	laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals	Dangerous

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SECTION 13: DISPOSAL CONSIDERATIONS (continued)

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

HP14 Ecotoxic, HP6 Acute Toxicity

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) 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: Contains Thiomersal

Seveso III:

Section	Description	Lower-tier requirements	Upper-tier requirements
H2		50	200

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 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) No 1907/2006 (Regulation (EC) No 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:

H373: May cause damage to organs through prolonged or repeated exposure

H412: Harmful to aquatic life with long lasting effects

H310: Fatal in contact with skin

H331: Toxic if inhaled

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SECTION 16: OTHER INFORMATION (continued)

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. 1: H310 - Fatal in contact with skin
Acute Tox. 2: H300+H330 - Fatal if swallowed or if inhaled
Aquatic Acute 1: H400 - Very toxic to aquatic life
Aquatic Chronic 1: H410 - Very toxic to aquatic life with long lasting effects
Eye Irrit. 2: H319 - Causes serious eye irritation
STOT RE 2: H373 - May cause damage to organs through prolonged or repeated exposure

Classification procedure:

STOT RE 2: Calculation method
Aquatic Chronic 3: Calculation method
Acute Tox. 2: Calculation method
Acute Tox. 3: Calculation method

Advice related to training:

Minimal 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 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 -