

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

- 1.1 Product identifier:** 1920 - Mitomycin C ≥97%
RTECS: CN0700000
Mitomycin
CAS: 50-07-7
EC: 200-008-6
Index: Non-applicable
REACH: Non-applicable
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. 2: Acute toxicity if swallowed, Category 2, H300
Carc. 2: Carcinogenicity, Category 2, H351
- 2.2 Label elements:**
CLP Regulation (EC) No 1272/2008:
Danger

Hazard statements:
Acute Tox. 2: H300 - Fatal if swallowed.
Carc. 2: H351 - Suspected of causing cancer.
Precautionary statements:
P201: Obtain special instructions before use.
P264: Wash thoroughly after handling.
P301+P310: IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P308+P313: IF exposed or concerned: Get medical advice/attention.
P330: Rinse mouth.
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.

*** 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)

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
CAS: 50-07-7 EC: 200-008-6 Index: Non-applicable REACH: Non-applicable	Mitomycin Regulation 1272/2008 Acute Tox. 2: H300; Carc. 2: H351 - Danger	Self-classified  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:

Request medical assistance immediately, 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:

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

By eye contact:

This product does not contain substances classified as hazardous for eye contact. Rinse eyes thoroughly for at least 15 minutes with lukewarm water, ensuring that the person affected does not rub or close their eyes.

By ingestion/aspiration:

Request medical assistance immediately, showing the SDS of this product. Induce vomiting (ONLY IF PERSON IS CONSCIOUS!) and then ingest large quantities of liquid to dilute the toxin. 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.

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:

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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. 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:

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:

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 use.

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

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.

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

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

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	 CAT II	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
 Mandatory complete 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

Emergency measure	Standards	Emergency measure	Standards
 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:

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

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 ³ (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:	Solid
Appearance:	Not available
Colour:	Ultramarine
Odour:	Not available
Odour threshold:	Non-applicable *

Volatility:

Boiling point at atmospheric pressure:	532 °C
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:	1900 kg/m ³
Relative density at 20 °C:	1,9
Dynamic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 40 °C:	Non-applicable *
Concentration:	Non-applicable *
pH:	Non-applicable *
Vapour density at 20 °C:	Non-applicable *
Partition coefficient n-octanol/water 20 °C:	-0,4
Solubility in water at 20 °C:	5 kg/m ³
Solubility properties:	Non-applicable *
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	360 °C

Flammability:

Flash Point:	276 °C
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:

*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)

Median equivalent diameter:	Non-applicable *
9.2 Other information:	
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 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
Notapplicable	Notapplicable	Notapplicable	Notapplicable	Notapplicable

10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Notapplicable	Avoid direct impact	Notapplicable	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 hazard classes as defined in Regulation (EC) No 1272/2008:

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 : Can be fatal if consumed. For more information see section 2.
- 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, 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):

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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 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: Exposure to this product can cause cancer. For more specific information on the possible health effects see section 2.
IARC: Mitomycin (2B)
 - 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: 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

Product-specific toxicological information:

Acute toxicity		Genus
LD50 oral	30 mg/kg	Rat

Specific toxicology information on the substances:

Identification	Acute toxicity	Genus
Mitomycin	LD50 oral	5 mg/kg
CAS: 50-07-7	LD50 dermal	Non-applicable
EC: 200-008-6	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

12.1 Toxicity:

Not available

12.2 Persistence and degradability:

Not available

12.3 Bioaccumulative potential:

Not available

12.4 Mobility in soil:

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SECTION 12: ECOLOGICAL INFORMATION (continued)

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):

HP6 Acute Toxicity, HP7 Carcinogenic

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 **

Transport of dangerous goods by land:

With regard to ADR 2021 and RID 2021:



14.1	UN number or ID number:	UN3462
14.2	UN proper shipping name:	TOXINS, EXTRACTED FROM LIVING SOURCES, SOLID, N.O.S. (Mitomycin)
14.3	Transport hazard class(es):	6.1
	Labels:	6.1
14.4	Packing group:	II
14.5	Environmental hazards:	No
14.6	Special precautions for user	
	Special regulations:	210, 274
	Tunnel restriction code:	C/E
	Physico-Chemical properties:	see section 9
	Limited quantities:	500 g
14.7	Maritime transport in bulk according to IMO instruments:	Non-applicable

Transport of dangerous goods by sea:

With regard to IMDG 40-20:

** Changes with regards to the previous version



SECTION 14: TRANSPORT INFORMATION ** (continued)



14.1	UN number or ID number:	UN3462
14.2	UN proper shipping name:	TOXINS, EXTRACTED FROM LIVING SOURCES, SOLID, N.O.S. (Mitomycin)
14.3	Transport hazard class(es):	6.1
	Labels:	6.1
14.4	Packing group:	II
14.5	Marine pollutant:	No
14.6	Special precautions for user	
	Special regulations:	210, 274
	EmS Codes:	F-A, S-A
	Physico-Chemical properties:	see section 9
	Limited quantities:	500 g
	Segregation group:	Non-applicable
14.7	Maritime transport in bulk according to IMO instruments:	Non-applicable

Transport of dangerous goods by air:

With regard to IATA/ICAO 2022:



14.1	UN number or ID number:	UN3462
14.2	UN proper shipping name:	TOXINS, EXTRACTED FROM LIVING SOURCES, SOLID, N.O.S. (Mitomycin)
14.3	Transport hazard class(es):	6.1
	Labels:	6.1
14.4	Packing group:	II
14.5	Environmental hazards:	No
14.6	Special precautions for user	
	Physico-Chemical properties:	see section 9
14.7	Maritime transport in bulk according to IMO instruments:	Non-applicable

** Changes with regards to the previous version

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:

Section	Description	Lower-tier requirements	Upper-tier requirements
H2	ACUTE TOXIC	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:

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SECTION 15: REGULATORY INFORMATION (continued)

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

TRANSPORT INFORMATION (SECTION 14):

- UN number
- Packing group

Texts of the legislative phrases mentioned in section 2:

H300: Fatal if swallowed.

H351: Suspected of causing cancer.

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. 2: H300 - Fatal if swallowed.

Carc. 2: H351 - Suspected of causing cancer.

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 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 -