



## Safety data sheet

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

### BioWest - Lymphosep, Lymphocyte Separation Media L0560

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

**1.1 Product identifier:** BioWest - Lymphosep, Lymphocyte Separation Media  
L0560

**Other means of identification:**

SRN : FR-MF000024000

IUD-ID (L0560-100) : 03770026925003

IUD-ID (L0560-500) : 03770026925010

**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:**

Biowest SAS

Rue de la Caille

49340 Nuaillé - France

Phone: 00 33 2 41 46 42 42 - Fax: 00 33 2 41 46 40 50

biowest@biowest.net

www.biowest.net

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

#### SECTION 2: HAZARDS IDENTIFICATION

**2.1 Classification of the substance or mixture:**

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

The product is not classified as hazardous according to CLP Regulation (EC) No 1272/2008.

**2.2 Label elements:**

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

None

**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

**3.1 Substance:**

Non-applicable

**3.2 Mixture:**

**Chemical description:** Water-based mixture of inorganic and organic compounds

**Components:**

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

Identification	Chemical name/Classification	Concentration
CAS: 1310-73-2 EC: 215-185-5 Index: 011-002-00-6 REACH: 01-2119457892-27-XXXX	<b>sodium hydroxide<sup>(1)</sup></b> Self-classified Regulation 1272/2008 Eye Dam. 1: H318; Met. Corr. 1: H290; Skin Corr. 1A: H314 - Danger	<1 %

<sup>(1)</sup> Substances presenting a health or environmental hazard which meet criteria laid down in Regulation (EU) No. 2020/878

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

**Other information:**

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#### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continued)

Identification	Specific concentration limit
sodium hydroxide CAS: 1310-73-2 EC: 215-185-5	% (w/w) $\geq 0,1$ : Met. Corr. 1 - H290 % (w/w) $\geq 5$ : Skin Corr. 1A - H314 $2 \leq$ % (w/w) $< 5$ : Skin Corr. 1B - H314 $0,5 \leq$ % (w/w) $< 2$ : Skin Irrit. 2 - H315 % (w/w) $\geq 2$ : Eye Dam. 1 - H318 $0,5 \leq$ % (w/w) $< 2$ : Eye Irrit. 2 - H319

#### 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:

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

##### By eye contact:

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

##### 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:

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.

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### 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 spilled 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

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 are no applicable occupational exposure limits for the substances contained in the product

##### DNEL (Workers):

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**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)**

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
sodium hydroxide CAS: 1310-73-2 EC: 215-185-5	Oral	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Dermal	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Inhalation	Non-applicable	Non-applicable	Non-applicable	1 mg/m <sup>3</sup>

**DNEL (General population):**

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
sodium hydroxide CAS: 1310-73-2 EC: 215-185-5	Oral	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Dermal	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Inhalation	Non-applicable	Non-applicable	Non-applicable	1 mg/m <sup>3</sup>

**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

The use of protection equipment will be necessary if a mist forms or if the occupational exposure limits are exceeded.

C.- Specific protection for the hands

Non-applicable

D.- Eye and face protection

Non-applicable

E.- Body protection

Non-applicable

F.- Additional emergency measures

It is not necessary to take additional emergency measures.

**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

\*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)**

Colour:	Colourless
Odour:	Not available
Odour threshold:	Non-applicable *
<b>Volatility:</b>	
Boiling point at atmospheric pressure:	100 °C
Vapour pressure at 20 °C:	2350 Pa
Vapour pressure at 50 °C:	12381,01 Pa (12,38 kPa)
Evaporation rate at 20 °C:	Non-applicable *
<b>Product description:</b>	
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:	Non-applicable *
Concentration:	Non-applicable *
pH:	6,5 - 7,5
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 *
<b>Flammability:</b>	
Flash Point:	Non Flammable (>60 °C)
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 *
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:**

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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 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	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Precaution	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. However, it does 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 does 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: Based on available data, the classification criteria are not met. However, it contains 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. However, it does 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: 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.

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**BioWest - Lymphosep, Lymphocyte Separation Media  
L0560****SECTION 11: TOXICOLOGICAL INFORMATION (continued)****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:**

Not available

**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

**12.1 Toxicity:****Acute toxicity:**

Identification	Concentration	Species	Genus
sodium hydroxide	LC50 189 mg/L (48 h)	Leuciscus idus	Fish
CAS: 1310-73-2	EC50 33 mg/L	Crangon crangon	Crustacean
EC: 215-185-5	EC50 Non-applicable		

**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:**

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**SECTION 13: DISPOSAL CONSIDERATIONS (continued)**

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:**

With regard to ADR 2021 and RID 2021:

- 14.1 UN number or ID number:** Non-applicable
- 14.2 UN proper shipping name:** Non-applicable
- 14.3 Transport hazard class(es):** Non-applicable
- Labels: Non-applicable
- 14.4 Packing group:** Non-applicable
- 14.5 Environmental hazards:** No
- 14.6 Special precautions for user**
- Special regulations: Non-applicable
- Tunnel restriction code: Non-applicable
- Physico-Chemical properties: see section 9
- Limited quantities: Non-applicable
- 14.7 Maritime transport in bulk according to IMO instruments:** Non-applicable

**Transport of dangerous goods by sea:**

With regard to IMDG 40-20:

- 14.1 UN number or ID number:** Non-applicable
- 14.2 UN proper shipping name:** Non-applicable
- 14.3 Transport hazard class(es):** Non-applicable
- Labels: Non-applicable
- 14.4 Packing group:** Non-applicable
- 14.5 Marine pollutant:** No
- 14.6 Special precautions for user**
- Special regulations: Non-applicable
- EmS Codes:
- Physico-Chemical properties: see section 9
- Limited quantities: Non-applicable
- 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 2023:

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#### SECTION 14: TRANSPORT INFORMATION (continued)

<b>14.1 UN number or ID number:</b>	Non-applicable
<b>14.2 UN proper shipping name:</b>	Non-applicable
<b>14.3 Transport hazard class(es):</b>	Non-applicable
Labels:	Non-applicable
<b>14.4 Packing group:</b>	Non-applicable
<b>14.5 Environmental hazards:</b>	No
<b>14.6 Special precautions for user</b>	
Physico-Chemical properties:	see section 9
<b>14.7 Maritime transport in bulk according to IMO instruments:</b>	Non-applicable

#### 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

##### 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:

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).

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

COMMISSION REGULATION (EU) 2020/878

##### 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:

Eye Dam. 1: H318 - Causes serious eye damage.

Met. Corr. 1: H290 - May be corrosive to metals.

Skin Corr. 1A: H314 - Causes severe skin burns and eye damage.

##### 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.

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#### **SECTION 16: OTHER INFORMATION (continued)**

**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 -