

**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

UFI: C420-40VQ-W00G-QYDH

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

Relevant uses: Used in biotechnology

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:

Classification of this product has been carried out in accordance with CLP Regulation (EC) No 1272/2008.

Eye Irrit. 2: Eye irritation, Category 2, H319

Skin Irrit. 2: Skin irritation, Category 2, H315

2.2 Label elements:

CLP Regulation (EC) No 1272/2008:

Warning



Hazard statements:

Eye Irrit. 2: H319 - Causes serious eye irritation.

Skin Irrit. 2: H315 - Causes skin irritation.

Precautionary statements:

P264: Wash thoroughly after handling.

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

P302+P352: IF ON SKIN: Wash with plenty of water.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P321: Specific treatment is urgently needed (go to see a doctor with the Safety data sheet for this product).

P332+P313: If skin irritation occurs: Get medical advice/attention.

P337+P313: If eye irritation persists: Get medical advice/attention.

P362+P364: Take off contaminated clothing and wash it before reuse.

2.3 Other hazards:

Product does not meet PBT/vPvB criteria

Endocrine-disrupting properties: The product does not meet the criteria.

** Changes with regards to the previous version

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS **

3.1 Substance:

** Changes with regards to the previous version

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

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	sodium hydroxide⁽¹⁾ ATP CLP00 Regulation 1272/2008 Skin Corr. 1A: H314 - Danger	<1 %

⁽¹⁾ 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:

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

** Changes with regards to the previous version

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:

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:

Not relevant

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:

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SECTION 5: FIREFIGHTING MEASURES (continued)

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.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

For non-emergency personnel:

Isolate leaks provided that there is no additional risk for the people performing this task. Personal protection equipment must be used against potential contact with the spilt product (See section 8). Evacuate the area and keep out those who do not have protection.

For emergency responders:

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

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and ground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- General precautions for safe use

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

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

Product is non-flammable under normal conditions of storage, handling and use. It is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that can affect flammable products. Consult section 10 for information on conditions and materials that should be avoided.

C.- Technical recommendations on general occupational hygiene

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

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

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SECTION 7: HANDLING AND STORAGE (continued)

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):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
sodium hydroxide	Oral	Not relevant	Not relevant	Not relevant	Not relevant
CAS: 1310-73-2	Dermal	Not relevant	Not relevant	Not relevant	Not relevant
EC: 215-185-5	Inhalation	Not relevant	Not relevant	Not relevant	1 mg/m ³

DNEL (General population):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
sodium hydroxide	Oral	Not relevant	Not relevant	Not relevant	Not relevant
CAS: 1310-73-2	Dermal	Not relevant	Not relevant	Not relevant	Not relevant
EC: 215-185-5	Inhalation	Not relevant	Not relevant	Not relevant	1 mg/m ³

PNEC:

Not relevant

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

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory hand protection	Chemical protective gloves (Material: Linear low-density polyethylene (LLDPE), Breakthrough time: > 480 min, Thickness: 0.062 mm)		EN ISO 21420:2020	Replace the gloves at any sign of deterioration.

As the product is a mixture of several substances, the resistance of the glove material can not be calculated in advance with total reliability and has therefore to be checked prior to the application.

D.- Eye and face protection



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

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

E.- Body protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing			Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 6529:2013, EN ISO 6530:2005, EN ISO 13688:2013, EN 464:1994.
	Anti-slip work shoes		EN ISO 20347:2012	Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 20345:2012 y EN 13832-1:2007

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:

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:	Not relevant
Average molecular weight:	Not relevant

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C:	Liquid
Appearance:	Fluid
Colour:	Colourless
Odour:	Not available
Odour threshold:	Not relevant *

Volatility:

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:	Not relevant *

Product description:

Density at 20 °C:	Not relevant *
Relative density at 20 °C:	Not relevant *
Dynamic viscosity at 20 °C:	Not relevant *
Kinematic viscosity at 20 °C:	Not relevant *
Kinematic viscosity at 40 °C:	Not relevant *

*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)

Concentration:	Not relevant *
pH:	6,5 - 7,5
Vapour density at 20 °C:	Not relevant *
Partition coefficient n-octanol/water 20 °C:	Not relevant *
Solubility in water at 20 °C:	Not relevant *
Solubility properties:	Not relevant *
Decomposition temperature:	Not relevant *
Melting point/freezing point:	Not relevant *
Flammability:	
Flash Point:	Non Flammable (>60 °C)
Flammability (solid, gas):	Not relevant *
Autoignition temperature:	Not relevant *
Lower flammability limit:	Not relevant *
Upper flammability limit:	Not relevant *
Particle characteristics:	
Median equivalent diameter:	Non-applicable

9.2 Other information:

Information with regard to physical hazard classes:

Explosive properties:	Not relevant *
Oxidising properties:	Not relevant *
Corrosive to metals:	Not relevant *
Heat of combustion:	Not relevant *
Aerosols-total percentage (by mass) of flammable components:	Not relevant *

Other safety characteristics:

Surface tension at 20 °C:	Not relevant *
Refraction index:	Not relevant *

*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 from Safety Data Sheet.

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 (CO₂), carbon monoxide and other organic compounds.

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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: 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. 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: Produces skin inflammation.
- Contact with the eyes: Produces eye damage after contact.

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: Not relevant
- 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:

Not relevant

Specific toxicology information on the substances:

Not available

11.2 Information on other hazards:

Endocrine disrupting properties

Endocrine-disrupting properties: The product does not meet the criteria.

Other information

Not relevant

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SECTION 12: ECOLOGICAL INFORMATION **

The experimental information related to the eco-toxicological properties of the product itself is not available
Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect.
For more information see section 3.

12.1 Toxicity:

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	Not relevant		

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 does not meet PBT/vPvB criteria

12.6 Endocrine disrupting properties:

Endocrine-disrupting properties: The product does not meet the criteria.

12.7 Other adverse effects:

Not described

*** Changes with regards to the previous version*

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Code	Description	Waste class (Regulation (EU) No 1357/2014)
16 05 09	discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08	Non-hazardous

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

Not relevant

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-hazardous 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:

*** Changes with regards to the previous version*

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SECTION 15: REGULATORY INFORMATION ** (continued)

- Article 95, REGULATION (EU) No 528/2012: Not relevant
- Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Not relevant
- Regulation (EC) No 1005/2009, about substances that deplete the ozone layer: Not relevant
- REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Not relevant
- Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Not relevant

Seveso III:

Not relevant

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

Shall not be used in:

- ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,
- tricks and jokes,
- games for one or more participants, or any article intended to be used as such, even with ornamental aspects.

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

** Changes with regards to the previous version

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.:

COMPOSITION/INFORMATION ON INGREDIENTS (SECTION 3, SECTION 12):

- New declared substances
sodium hydroxide (1310-73-2)
- Removed substances
sodium hydroxide (1310-73-2)

CLP Regulation (EC) No 1272/2008 (SECTION 2, SECTION 16):

- Pictograms
- Hazard statements
- Precautionary statements

REGULATORY INFORMATION (SECTION 15):

- Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc)

Texts of the legislative phrases mentioned in section 2:

H315: Causes skin irritation.

H319: Causes serious eye irritation.

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:

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

Classification procedure:

Skin Irrit. 2: Calculation method

Eye Irrit. 2: Calculation method

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:

** Changes with regards to the previous version

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<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

*** Changes with regards to the previous version*

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 -