

SAFETY DATA SHEET

(According to Regulation (EC) No. 1907/2006 (REACH) and the modifications by Regulations (EC) No. 1272/2008 (CLP), (EU) 2015/830 and (EU) 2020/878)

FAKOLITH®

FAKOLITH FK 11

Version 1 Date of compilation: 25/09/2025
Version 3 (replaces version 2)

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

1.1 Product identifier.

Product Name: FAKOLITH FK 11
UFI: 9EGF-SC5G-F8SC-5QW7

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

Industrial use
Cleaner
Professional use

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

Company: **Fakolith Farben GmbH**
Address: Carl-Benz-Str. 19
City: D-64658 - Fürth/ Odw.
Province: Hesse
Telephone: +49 (0) 6253/ 2394-0
Fax: +49 (0) 6253/ 2394-10
E-mail: info@fakolith.com
Web: www.fakolith.com

Information Department:
Germany: Uwe Farenkopf (germanyfakolith.com)
Tel. + 49 (0) 6253 / 2394-0 Fax: +49 (0) 6253 / 2394-10

1.4 Emergency telephone number:

 (Only available during office hours; Monday-Friday; 08:00-18:00)

Spain: +34 (0) 915 620 420
Germany: +49 (0) 61 31 19 240
Austria: +43 (0) 14 06 43 43
Switzerland: +41 (0) 44 25 15 151
Italy: +39 (0) 26 44 42 523

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the substance or mixture.

In accordance with Regulation (EC) No 1272/2008:

Eye Dam. 1 : Causes serious eye damage.
Skin Corr. 1B : Causes severe skin burns and eye damage.

2.2 Label elements.

Labelling in accordance with Regulation (EC) No 1272/2008:

Pictograms:



Signal Word:

Danger

Hazard statements:

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H314 Causes severe skin burns and eye damage.

Precautionary statements:

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P264 Wash thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

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

P310 Immediately call a POISON CENTER or doctor.

Contains:

sodium hydroxide, caustic soda
hexyl D-glucoside

2.3 Other hazards.

The mixture does not contain substances classified as PBT.

The mixture does not contain substances classified as vPvB.

The mixture does not contain any endocrine disrupting properties substances.

In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

3.1 Substances.

Not applicable.

3.2 Mixtures.

Substances posing a danger to health or the environment in accordance with the Regulation (EC) No. 1272/2008, assigned a Community exposure limit in the workplace, and classified as PBT/vPvB or included in the Candidate List:

Identifiers	Name	Concentrate	(*)Classification - Regulation (EC) No 1272/2008	
			Classification	Specifics concentration limits and Acute toxicity estimate
CAS No: 68439-46-3 Registration No: 01-2119980051-45-XXXX	Alcohols, C9-11, ethoxylated	1 - 10 %	Eye Irrit. 2, H319	-
CAS No: 54549-24-5 EC No: 259-217-6 Registration No: 01-2119492545-29-XXXX	hexyl D-glucoside	1 - 3 %	Eye Dam. 1, H318	-
Index No: 011-002-00-6 CAS No: 1310-73-2 EC No: 215-185-5 Registration No: 01-2119457892-27-XXXX	sodium hydroxide, caustic soda	2 - 5 %	Skin Corr. 1A, H314: C ≥ 5 % Skin Corr. 1B, H314: 2 % ≤ C < 5 % Skin Irrit. 2, H315: 0,5 % ≤ C < 2 % Eye Irrit. 2, H319: 0,5 % ≤ C < 2 %	Skin Corr. 1A, H314

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CAS No: 68891-38-3 EC No: 500-234-8 Registration No: 01-2119488639-16-XXXX	Alcohols, C12-14, ethoxylated, sulfates, sodium salts	1 - 5 %	Aquatic Chronic 3, H412 - Eye Dam. 1, H318 - Skin Irrit. 2, H315	Eye Irrit. 2, H319: 5 % ≤ C < 10 % Eye Dam. 1, H318: C ≥ 10 %
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(*) The complete text of the H phrases is given in section 16 of this Safety Data Sheet.

SECTION 4: FIRST AID MEASURES.

4.1 Description of first aid measures.

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

Inhalation.

Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

Eye contact.

Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance. Dont let the person to rub the affected eye.

Skin contact.

Remove contaminated clothing. Wash skin vigorously with water and soap or a suitable skin cleaner. NEVER use solvents or thinners. The use of personal protective equipment is recommended for people providing first aid (see section 8).

Ingestion.

If accidentally ingested, seek immediate medical attention. Keep calm. NEVER induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed.

Corrosive Product, contact with eyes or skin can cause burns; ingestion or inhalation can cause internal damage, if this occurs immediate medical assistance is required.

Contact with eyes may cause irreversible damage.

4.3 Indication of any immediate medical attention and special treatment needed.

Request immediate medical attention. Never administer anything orally to persons who are unconscious. Do not induce vomiting. If the person vomits, clear the respiratory tract. Cover the affected area with a dry sterile bandage. Protect the affected area from pressure or friction.

SECTION 5: FIREFIGHTING MEASURES.

The product is NOT classified as flammable, in case of fire the following measures should be taken:

5.1 Extinguishing media.

Suitable extinguishing media:

Extinguisher powder or CO2. In case of more serious fires, also alcohol-resistant foam and water spray.

Unsuitable extinguishing media:

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

5.2 Special hazards arising from the substance or mixture.

Special risks.

Exposure to combustion or decomposition products can be harmful to your health.

5.3 Advice for firefighters.

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account. Prevent the products used to fight the fire from going into drains, sewers, or waterways.

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Fire protection equipment.

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

SECTION 6: ACCIDENTAL RELEASE MEASURES.

6.1 Personal precautions, protective equipment and emergency procedures.

For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions.

Product not classified as hazardous for the environment, avoid spillage as much as possible.

6.3 Methods and material for containment and cleaning up.

Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant.

Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations (see section 13).

6.4 Reference to other sections.

For exposure control and individual protection measures, see section 8.

For later elimination of waste, follow the recommendations under section 13.

SECTION 7: HANDLING AND STORAGE.

7.1 Precautions for safe handling.

For personal protection, see section 8.

In the application area, smoking, eating, and drinking must be prohibited.

Follow legislation on occupational health and safety.

Never use pressure to empty the containers. They are not pressure-resistant containers. Keep the product in containers made of a material identical to the original.

7.2 Conditions for safe storage, including any incompatibilities.

Store according to local legislation. Observe indications on the label. Store the containers between 5 and 25 ° C, in a dry and well-ventilated place, far from sources of heat and direct solar light. Keep far away from ignition points. Keep away from oxidising agents and from highly acidic or alkaline materials. Do not smoke. Prevent the entry of non-authorised persons. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

The product is not affected by Directive 2012/18/EU (SEVESO III).

Storage class (LGK): 8B Non-flammable corrosive hazardous substances

7.3 Specific end use(s).

Not available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 Control parameters.

Work exposure limit for:

Name	CAS No.	Country	Limit value	ppm	mg/m ³
1,4-dioxane	123-91-1	European Union [1]	Eight hours Short term	20	73

[1] According both Binding Occupational Exposure Limits (BOELVs) and Indicative Occupational Exposure Limits (IOELVs) adopted by Scientific Committee for Occupational Exposure Limits to Chemical Agents (SCOEL).

The product does NOT contain substances with Biological Limit Values.

Concentration levels DNEL/DMEL:

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Name	DNEL/DMEL	Type	Value
hexyl D-glucoside CAS No: 54549-24-5 EC No: 259-217-6	DNEL (Workers)	Inhalation, Chronic, Systemic effects	420 (mg/m ³)
sodium hydroxide, caustic soda CAS No: 1310-73-2 EC No: 215-185-5	DNEL (Workers)	Inhalation, Chronic, Local effects	1 (mg/m ³)
	DNEL (Consumers)	Inhalation, Chronic, Local effects	1 (mg/m ³)

DNEL: Derived No Effect Level, level of exposure to the substance below which adverse effects are not anticipated.

DMEL: Derived Minimal Effect Level, exposure level corresponding to a low risk, that risk should be considered a tolerable minimum.

8.2 Exposure controls.

Measures of a technical nature:

Provide adequate ventilation, which can be achieved by using good local exhaust-ventilation and a good general exhaust system.

Concentration:	100 %		
Uses:	Industrial use Cleaner Professional use		
Breathing protection:			
PPE: Filter mask for protection against gases and particles.			
Characteristics:	«CE» marking, category III. The mask must have a wide field of vision and an anatomically designed form in order to be sealed and watertight.		
CEN standards:	EN 136, EN 140, EN 405		
Maintenance:	Should not be stored in places exposed to high temperatures and damp environments before use. Special attention should be paid to the state of the inhalation and exhalation valves in the face adaptor.		
Observations:	Read carefully the manufacturer's instructions regarding the equipment's use and maintenance. Attach the necessary filters to the equipment according to the specific nature of the risk (Particles and aerosols: P1-P2-P3, Gases and vapours: A-B-E-K-AX), changing them as advised by the manufacturer.		
Filter Type needed:	A2		
Hand protection:			
PPE:	Non-disposable protective gloves against chemicals.		
Characteristics:	«CE» marking, category III. Check the list of chemicals for which the glove has been tested.		
CEN standards:	EN 374-1, En 374-2, EN 374-3, EN 420		
Maintenance:	A schedule for the periodical replacement of gloves should be established in order to guarantee their replacement before pollutants permeate them. The use of contaminated gloves could be more dangerous than not using gloves, since the pollutant can gradually accumulate in the glove's material.		
Observations:	They are to be replaced whenever tears, cracks or deformations are observed or when exterior dirt could reduce their strength.		
Material:	PVC (polyvinyl chloride)	Breakthrough time (min.):	Material thickness (mm): 0,35
Eye protection:			
PPE:	Protective goggles with built-in frame.		
Characteristics:	«CE» marking, category II. Eye protector with built-in frame for protection against dust, smoke, fog and vapour.		
CEN standards:	EN 165, EN 166, EN 167, EN 168		
Maintenance:	Visibility through lenses should be ideal. Therefore, these parts should be cleaned daily. Protectors should be disinfected periodically following the manufacturer's instructions.		
Observations:	Some signs of wear and tear include: yellow colouring of the lenses, superficial scratching of the lenses, scraping etc.		
Skin protection:			
PPE:	Chemical protective clothing		
Characteristics:	«CE» marking, category III. Clothing should fit properly. The level of protection must be set according to a test parameter called BT (Breakthrough Time), which indicates how long it takes for the chemical to pass through the material.		
CEN standards:	EN 464,EN 340, EN 943-1, EN 943-2, EN ISO 6529, EN ISO 6530, EN 13034		
Maintenance:	In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer.		

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Observations:	The protective clothing's design should facilitate correct positioning, staying in place without moving for the period of use expected, bearing in mind environmental factors as well as any movement or position the user might adopt while carrying out the activity.
PPE:	Anti-static safety footwear against chemicals.
Characteristics:	«CE» marking, category III. Check the list of chemicals against which the footwear is resistant.
CEN standards:	EN ISO 13287, EN 13832-1, EN 13832-2, EN 13832-3, EN ISO 20344, EN ISO 20345
Maintenance:	For correct maintenance of this kind of safety footwear, it is necessary to observe the instructions specified by the manufacturer. The footwear should be replaced as soon as any sign of damage is observed.
Observations:	The footwear should be cleaned regularly and dried when damp, although it should not be placed too close to a source of heat in order to avoid any sharp changes in temperature.



SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Physical state: Liquid

Colour: Amber

Odour: Characteristic

Odour threshold: Not applicable/Not available due to the nature/properties of the product

Melting point: Not applicable/Not available due to the nature/properties of the product

Freezing point: Not applicable/Not available due to the nature/properties of the product

Boiling point or initial boiling point and boiling range: 132 °C (Estimation based on the indication of the Regulation (CE) N°1272/2008.)

Flammability: Not applicable/Not available due to the nature/properties of the product

Lower explosion limit: Not applicable/Not available due to the nature/properties of the product

Upper explosion limit: Not applicable/Not available due to the nature/properties of the product

Flash point: 224 °C (Estimation based on the indication of the Regulation (CE) N°1272/2008.)

Auto-ignition temperature: Not applicable/Not available due to the nature/properties of the product

Decomposition temperature: Not applicable/Not available due to the nature/properties of the product

pH: 14 (100%)

Kinematic viscosity: Not applicable/Not available due to the nature/properties of the product

Solubility: Not applicable/Not available due to the nature/properties of the product

Hydrosolubility: Not applicable/Not available due to the nature/properties of the product

Liposolubility: Not applicable/Not available due to the nature/properties of the product

Partition coefficient n-octanol/water (log value): Not applicable/Not available due to the nature/properties of the product

Vapour pressure: 23,299 (Estimation based on the indication of the Regulation (CE) N°1272/2008.)

Absolute density: Not applicable/Not available due to the nature/properties of the product

Relative density: 1,05

Relative vapour density: Not applicable/Not available due to the nature/properties of the product

Particle characteristics: Not applicable/Not available due to the nature/properties of the product

9.2 Other information

Not applicable/Not available due to the nature/properties of the product

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.

The product does not present hazards by their reactivity.

10.2 Chemical stability.

Stable under the recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions.

The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid.

Avoid any improper handling.

10.5 Incompatible materials.

Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

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10.6 Hazardous decomposition products.

No decomposition if used for the intended uses.

SECTION 11: TOXICOLOGICAL INFORMATION.

11.1 Information on hazard classes as defined in Regulation (EC) Nº 1272/2008.

Splashes in the eyes can cause serious and irreversible damage.

Toxicological information about the substances present in the composition.

Name	Acute toxicity			
	Type	Test	Kind	Value
sodium hydroxide, caustic soda	Oral	LD50	Rabbit	325 mg/kg bw [1]
		[1]	Naunyn-Schmiedeberg's experimentelle Pathologie und	(1937), Archiv für Pharmakologie (Berlin, Germany), 184, 587-604
	Dermal			
CAS No: 1310-73-2	Inhalation			
EC No: 215-185-5				

a) acute toxicity;
Not conclusive data for classification.

b) skin corrosion/irritation;
Product classified:
Skin Corrosive, Category 1B: Causes severe skin burns and eye damage.

c) serious eye damage/irritation;
Product classified:
Serious eye damage, Category 1: Causes serious eye damage.

d) respiratory or skin sensitisation;
Not conclusive data for classification.

e) germ cell mutagenicity;
Not conclusive data for classification.

f) carcinogenicity;
Not conclusive data for classification.

g) reproductive toxicity;
Not conclusive data for classification.

h) STOT-single exposure;
Not conclusive data for classification.

i) STOT-repeated exposure;
Not conclusive data for classification.

j) aspiration hazard;
Not conclusive data for classification.

11.2 Information on other hazards.

Endocrine disrupting properties

This product does not contain components with endocrine-disrupting properties with effects on human health.

Other information

There is no information available on other adverse health effects.

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SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

Name	Ecotoxicity			
	Type	Test	Kind	Value
sodium hydroxide, caustic soda	Fish	Minimal Lethal Concentration	Notropis sp.	100 mg/L (120 h) [1]
		[1] Van Horn et al. (1949), Effects of Kraft Mill Wastes, American Fisheries Society		
	Aquatic invertebrates	LC50	Ophryotrocha diadema	33 mg/L (48 h) [1]
		[1] Parker JG (1984), Wat Res, 18, 865-868		
CAS No: 1310-73-2 EC No: 215-185-5		Aquatic plants		

12.2 Persistence and degradability.

No information is available regarding the biodegradability of the substances present.

No information is available on the degradability of the substances present.

No information is available about persistence and degradability of the product.

12.3 Bioaccumulative potential.

No information is available regarding the bioaccumulation of the substances present.

12.4 Mobility in soil.

No information is available about the mobility in soil.

The product must not be allowed to go into sewers or waterways.

Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment.

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties.

The substance/mixture does not contain components that are endocrine disruptors according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

12.7 Other adverse effects.

The product is not affected by the Regulation (EU) 2024/590 of the European Parliament and of the Council of 7 February 2024 on substances that deplete the ozone layer.

No information is available about other adverse effects for the environment.

SECTION 13: DISPOSAL CONSIDERATIONS.

13.1 Waste treatment methods.

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.

Follow the provisions of Directive 2008/98/EC regarding waste management.

Waste classification according to the European Waste Catalogue:

07 WASTES FROM ORGANIC CHEMICAL PROCESSES

07 06 wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics

07 06 99 wastes not otherwise specified

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SECTION 14: TRANSPORT INFORMATION.

Transport following ADR rules for road transport, RID rules for railway, ADN for inner waterways, IMDG for sea, and ICAO/IATA for air transport.

Land: Transport by road: ADR, Transport by rail: RID.

Transport documentation: Consignment note and written instructions

Sea: Transport by ship: IMDG.

Transport documentation: Bill of lading

Air: Transport by plane: ICAO/IATA.

Transport document: Airway bill.

14.1 UN number or ID number.

UN No: UN1760

14.2 UN proper shipping name.

Description:

ADR/RID: UN 1760, CORROSIVE LIQUID, N.O.S. (CONTAINS SODIUM HYDROXIDE CAUSTIC SODA), 8, PG II, (E)

IMDG: UN 1760, CORROSIVE LIQUID, N.O.S. (CONTAINS SODIUM HYDROXIDE CAUSTIC SODA), 8, PG II

ICAO/IATA: UN 1760, CORROSIVE LIQUID, N.O.S. (CONTAINS SODIUM HYDROXIDE CAUSTIC SODA), 8, PG II

14.3 Transport hazard class(es).

Class(es): 8

14.4 Packing group.

Packing group: II

14.5 Environmental hazards.

Marine pollutant: No

Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): F-A,S-B

14.6 Special precautions for user.

Labels: 8



Hazard number: 80

Provisions concerning carriage in bulk ADR: Not authorized carriage in bulk in accordance with ADR.

Proceed in accordance with point 6.

ADR LQ: 1 L

IMDG LQ: 1 L

ICAO LQ: 0,5 L

14.7 Maritime transport in bulk according to IMO instruments.

The product is not transported in bulk.

SECTION 15: REGULATORY INFORMATION.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.

Volatile organic compound (VOC)

VOC content (p/p): 0,001 %

VOC content: 0,014 g/l

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Contains in accordance with Regulation (EC) No 648/2004 on detergents:

non-ionic surfactants

< 5%

anionic surfactants

< 5%

The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

Water hazard class (Germany): WGK 1: slightly hazardous to water. (Autoclassified according to the AwSV Regulations)

15.2 Chemical safety assessment.

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: OTHER INFORMATION.

Complete text of the H phrases that appear in section 3:

H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H412	Harmful to aquatic life with long lasting effects.

Classification codes:

Aquatic Chronic 3: Chronic effect to the aquatic environment, Category 3

Eye Dam. 1: Serious eye damage, Category 1

Eye Irrit. 2: Eye irritation, Category 2

Skin Corr. 1A: Skin Corrosive, Category 1A

Skin Corr. 1B: Skin Corrosive, Category 1B

Skin Irrit. 2: Skin irritant, Category 2

Changes regarding to the previous version:

- Modification in the values of the physical and chemical properties (SECTION 9).

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Physical hazards On basis of test data

Health hazards Calculation method

Environmental hazards Calculation method

It is advisable to carry out basic training with regard to health and safety at work in order to handle this product correctly.

Abbreviations and acronyms used:

ADR: Agreement concerning the International Carriage of Dangerous Goods by Road.

AwSV: Facility Regulations for handling substances that are hazardous for the water.

CEN: European Committee for Standardization.

DMEL: Derived Minimal Effect Level, exposure level corresponding to a low risk, that risk should be considered a tolerable minimum.

DNEL: Derived No Effect Level, level of exposure to the substance below which adverse effects are not anticipated.

EC50: Half maximal effective concentration.

PPE: Personal protection equipment.

IATA: International Air Transport Association.

ICAO: International Civil Aviation Organization.

IMDG: International Maritime Code for Dangerous Goods.

LC50: Lethal concentration, 50%.

LD50: Lethal dose, 50%.

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RID: Regulations Concerning the International Transport of Dangerous Goods by Rail.
WGK: Water hazard classes.

Key literature references and sources for data:
<http://eur-lex.europa.eu/homepage.html>
<http://echa.europa.eu/>
Regulation (EU) 2020/878.
Regulation (EC) No 1907/2006.
Regulation (EC) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemical substances and mixtures (REACH).

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.