

BIL T DCA 500_R1

Creation date	28th May 2015	Version	4.0
Revision date	26th January 2024		

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Substance / mixture	BIL T DCA 500_R1
Number	mixture
UFI	BLT00077
Other mixture names	UHWU-HW8S-9J5F-E7S3
	BIL T DCA 500; BILIRUBIN TOTAL DCA

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

Mixture's intended use
Diagnostic reagent for quantitative in vitro determination of Bilirubin Total in human serum and plasma.

Main intended use

PC-MED-OTH Other medical devices

Secondary uses

PC-TEC-19 Reagents and laboratory chemicals

The use descriptors

PC 21 Laboratory chemicals

Mixture uses advised against

The product should not be used in ways other than those referred in Section 1.

1.3. Details of the supplier of the safety data sheet**Manufacturer**

Name or trade name	Erba Lachema s.r.o.
Address	Karásek 2219/1d , Brno, 62100
	Czech Republic
Identification number (CRN)	26918846
VAT Reg No	CZ26918846
Phone	+420 517 077 111
E-mail	msds@erba.com
Web address	www.erbalachema.com

Competent person responsible for the safety data sheet

Name	Erba Lachema s.r.o.
E-mail	msds@erba.com

1.4. Emergency telephone number

European emergency number: 112 112

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification of the mixture in accordance with Regulation (EC) No 1272/2008**

The mixture is classified as dangerous.

Met. Corr. 1, H290
Skin Corr. 1, H314
Eye Dam. 1, H318
Aquatic Chronic 3, H412

Most serious adverse physico-chemical effects

May be corrosive to metals.

Most serious adverse effects on human health and the environment

Causes severe skin burns and eye damage.

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2.2. Label elements

Hazard pictogram



Signal word

Danger

Hazardous substances

Cetrimonium bromide
Oxtylphenoxypolyethoxy-ethanol
Octylphenol-ethoxylát

Hazard statements

H290 May be corrosive to metals.
H314 Causes severe skin burns and eye damage.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P280 Wear protective gloves/protective clothing/eye 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.
P337+P313 If eye irritation persists: Get medical advice/attention.

2.3. Other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Mixture does not contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Mixture of substances and additives specified below.

Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
Index: 017-002-01-X CAS: 7647-01-0 EC: 231-595-7	Hydrochloric acid 35%	1-5	Met. Corr. 1, H290 Skin Corr. 1B, H314 STOT SE 3, H335 Specific concentration limit: Skin Corr. 1B, H314: C ≥ 25 % Skin Irrit. 2, H315; Eye Irrit. 2, H319: 10 % ≤ C < 25 % STOT SE 3, H335: C ≥ 10 %	1
CAS: 57-09-0 EC: 200-311-3	Cetrimonium bromide	1-2	Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 1, H400	
CAS: 9002-93-1	Oxtylphenoxypolyethoxy-ethanol	<1	Acute Tox. 4, H302 Eye Dam. 1, H318 Aquatic Chronic 2, H411	2, 3
CAS: 9036-19-5	Octylphenol-ethoxylát	<1	Eye Dam. 1, H318	

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Notes

- 1 A substance for which exposure limits are set.
- 2 Substance of very high concern - SVHC.
- 3 The substance is included in Annex XIV of the REACH Regulation

Full text of all classifications and hazard statements is given in the section 16.

SECTION 4: First aid measures**4.1. Description of first aid measures**

Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet. If unconscious, put the person in the stabilized (recovery) position on his side with his head slightly bent backwards and make sure that airways are free; never induce vomiting. If the person vomits by himself, make sure that the vomit is not inhaled. In life threatening conditions first of all provide resuscitation of the affected person and ensure medical assistance. Respiratory arrest - provide artificial respiration immediately. Cardiac arrest - provide indirect cardiac massage immediately.

If inhaled

Take care of your own safety, do not let the affected person walk! Terminate the exposure immediately; move the affected person to fresh air. Beware of the contaminated clothes. Depending on the situation, call the medical rescue service and ensure medical treatment considering the frequent need of further observation for at least 24 hours.

If on skin

Remove contaminated clothes. Take off any rings, watches, bracelets before or during washing if worn in the contaminated areas of the skin. Depending on the situation, call the medical rescue service and always ensure medical treatment. Rinse contaminated areas with a flow of water, lukewarm at best, for 10-30 minutes; do not use any brush, soap or neutralizers. Rinse skin with water or shower. Rinse cautiously with water for several minutes.

If in eyes

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person. No neutralization should be performed in any case! Rinsing should be continued for 10-30 minutes from the inner to the outer eye corner to make sure that the other eye is not involved. Depending on the situation, call medical rescue service or ensure medical treatment as promptly as possible. Everyone must be referred for treatment even if affected only a little.

If swallowed

DO NOT INDUCE VOMITING - there is danger of further damage to the gastrointestinal tract!!! Danger of esophageal and gastric perforation! RINSE THE MOUTH WITH WATER IMMEDIATELY AND LET THE PERSON DRINK 2-5 dl of cold water to reduce the heating effect of the corrosive substance. Consuming larger amounts of liquid is not advisable as it may induce vomiting and potential inhaling of the corrosive substances in the lungs. The affected person must not be forced to drink, particularly if already feeling pain in the mouth or throat. In this case let the affected person only rinse the mouth with water. DO NOT PROVIDE ACTIVATED CARBON! Depending on the situation, call medical rescue service or ensure medical treatment as promptly as possible.

4.2. Most important symptoms and effects, both acute and delayed**If inhaled**

Inhaling vapours can cause corrosion of the breathing system.

If on skin

Causes severe skin burns.

If in eyes

Causes serious eye damage.

If swallowed

Corrosion of the digestion system can occur.

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

Symptomatic treatment.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist.

Unsuitable extinguishing media

Water - full jet.

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5.2. Special hazards arising from the substance or mixture

In case of fire, hazardous fumes may be produced. May develop in case of fire: Hydrochloric, hydrogen bromide (HBr), nitrogen oxides (NOx), carbon monoxide and carbon dioxide.

5.3. Advice for firefighters

Self-Contained Breathing Apparatus (SCBA) with a chemical protection suit only where personal (close) contact is likely. Use a self-contained breathing apparatus and full-body protective clothing. Do not allow run-off of contaminated fire extinguishing material to enter drains or surface and ground water. Hazchem-code: 2x

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Ensure good ventilation. May be corrosive to metals. Use personal protective equipment for work. Follow the instructions in the Sections 7 and 8. Do not inhale aerosols. Prevent contact with skin and eyes. Isolate and mark the spill site, order all the people out of the place, who do not participate in the rescue work. Use all recommended personal protective equipment during rescue work.

6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water.

6.3. Methods and material for containment and cleaning up

Spilled product should be covered with suitable (non-flammable) absorbing material (sand, diatomaceous earth, earth and other suitable absorption materials); to be contained in well closed containers and removed as per the Section 13. In the event of leakage of the substantial amount of the product, inform fire brigade and other competent bodies. After removal of the product, wash the contaminated site with plenty of water. Do not use solvents. Absorb spillage to prevent material damage.

6.4. Reference to other sections

See the Section 7, 8 and 13.

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Prevent formation of gases and vapours in concentrations exceeding the occupational exposure limits. Do not inhale aerosols. Prevent contact with skin and eyes. Wash hands and exposed parts of the body thoroughly after handling. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection. Observe the normal operating procedures for handling chemical substances and mixtures. Observe the principles of work in laboratory.

7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed containers in cold, dry and well ventilated areas designated for this purpose. Store locked up. Store only in the original package. Do not freeze. Keep out from heat and light. Unsuitable materials: Metals.

Storage temperature min 2 °C, max 8 °C

7.3. Specific end use(s)

The kit is designed for in vitro diagnostic devices.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

The mixture contains substances for which occupational exposure limits are set.

Czech Republic**Government Regulation 330/2023 Coll.**

Substance name (component)	Type	Value	Note
Hydrochloric acid 35% (CAS: 7647-01-0)	PEL	8 mg/m ³	irritating to mucous membranes (eyes, respiratory system) and skin
	PEL	5 ppm	
	NPK-P	15 mg/m ³	

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Czech Republic**Government Regulation 330/2023 Coll.**

Substance name (component)	Type	Value	Note
Hydrochloric acid 35% (CAS: 7647-01-0)	NPK-P	10 ppm	irritating to mucous membranes (eyes, respiratory system) and skin

European Union**Commission Directive 2000/39/EC**

Substance name (component)	Type	Value	Note
Hydrochloric acid 35% (CAS: 7647-01-0)	OEL 8 hours	8 mg/m ³	
	OEL 8 hours	5 ppm	
	OEL 15 minutes	15 mg/m ³	
	OEL 15 minutes	10 ppm	

DNEL

Hydrochloric acid 35%					
Workers / consumers	Route of exposure	Value	Effect	Value determination	Source
Workers	Inhalation	15.0 mg/m ³	Acute effects local		
Workers	Inhalation	8.0 mg/m ³	Chronic effects local		
Consumers	Inhalation	8.0 mg/m ³	Chronic effects local		
Consumers	Inhalation	15 mg/m ³	Acute effects local		

8.2. Exposure controls

Follow the usual measures intended for health protection at work and especially for good ventilation. This can be achieved only by local suction or efficient general ventilation. Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest.

Eye/face protection

Tightly sealed safety glasses according to EN 166.

Skin protection

Hand protection: Protective gloves resistant to the product. Protective gloves according to EN 374. Glove material: Nitrile rubber – layer thickness: 0.11 mm, Breakthrough time: > 480 min. When choosing appropriate thickness, material and permeability of the gloves, observe recommendations of their particular manufacturer. Observe other recommendations of the manufacturer. Other protection: protective workwear. Contaminated skin should be washed thoroughly.

Respiratory protection

If all workplace limits are observed and good ventilation is ensured, no special precautions necessary.

Thermal hazard

Not available.

Environmental exposure controls

To eliminate the emergency conditions, have pre-prepared a decontamination mixture and appropriate collection vessels for reaction residues. Dispose of reaction residues and decontaminated mixtures as hazardous waste water in accordance with relevant legal regulations.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	liquid
Colour	colourless
Odour	odourless without fragrance
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	data not available

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Flammability	non-flammable
Lower and upper explosion limit	data not available
Flash point	data not available
Auto-ignition temperature	data not available
Decomposition temperature	data not available
pH	0.75-0.85 (undiluted at 25 °C)
Kinematic viscosity	data not available
Solubility in water	data not available
Solubility in fats	data not available
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	
Density	1.012 g/cm ³
Relative vapour density	data not available
Particle characteristics	data not available
Form	Clear colourless liquid
9.2. Other information	
Evaporation rate	data not available

SECTION 10: Stability and reactivity**10.1. Reactivity**

May be corrosive to metals.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Unknown.

10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost. Protect from heat/light.

10.5. Incompatible materials

Protect against strong acids, bases and oxidizing agents. May be corrosive to metals.

10.6. Hazardous decomposition products

May develop in case of fire: Hydrochloric, hydrogen bromide (HBr), nitrogen oxides (NO_x), carbon monoxide and carbon dioxide.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

Inhalation of solvent vapors above values exceeding exposure limits for working environment may result in acute inhalation poisoning, depending on the level of concentration and exposure time. No toxicological data is available for the mixture.

Acute toxicity

Based on the available data, the criteria for classification of the mixture are not met. Data for the components of the mixture are not available.

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Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	ATE	16720 mg/kg				Calculation of value

Skin corrosion/irritation

Causes severe skin burns and eye damage. Data for the components of the mixture are not available.

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Serious eye damage/irritation

Causes serious eye damage. Causes severe skin burns and eye damage. Data for the components of the mixture are not available.

Respiratory or skin sensitisation

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Germ cell mutagenicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Carcinogenicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Reproductive toxicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Toxicity for specific target organ - single exposure

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Toxicity for specific target organ - repeated exposure

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Aspiration hazard

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

11.2. Information on other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 12: Ecological information**12.1. Toxicity**

Harmful effects on water organisms by modification of pH-value.

Acute toxicity

Cetrimonium bromide				
Parameter	Value	Exposure time	Species	Environment
EC ₅₀	0.03 mg/l	48 hours	Daphnia (Daphnia magna)	
LC ₅₀	0.3 mg/l	96 hours	Fish (Brachydanio rerio)	

Hydrochloric acid 35%				
Parameter	Value	Exposure time	Species	Environment
LC ₅₀	20.5 mg/l	96 hours	Fish	

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Oxtylphenoxypolyethoxy-ethanol				
Parameter	Value	Exposure time	Species	Environment
EC ₅₀	26 mg/l	48 hours	Daphnia (Daphnia magna)	
LC ₅₀	8.9 mg/l	96 hours	Fish (Pimephales promelas)	

12.2. Persistence and degradability

Cetrimonium bromide: Biodegradability: 100%/28 days. The product is easily disassembled.

12.3. Bioaccumulative potential

No data are available for either the mixture or the components.

12.4. Mobility in soil

No data are available for either the mixture or the components.

12.5. Results of PBT and vPvB assessment

Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

12.6. Endocrine disrupting properties

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

12.7. Other adverse effects

Do not allow to enter into ground-water, surface water or drains.

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

Waste management legislation

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

Waste type code

16 05 06* laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals

Packaging waste type code

15 01 10* packaging containing residues of or contaminated by hazardous substances

(*) - Hazardous waste according to Directive 2008/98/EC on hazardous waste

SECTION 14: Transport information**14.1. UN number or ID number**

UN 3264

14.2. UN proper shipping name

CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (Hydrochloric acid)

14.3. Transport hazard class(es)

8 Corrosive substances

14.4. Packing group

III

14.5. Environmental hazards

not relevant

14.6. Special precautions for user

Reference in the Sections 4 to 8.

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14.7. Maritime transport in bulk according to IMO instruments

not relevant

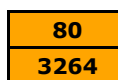
Additional information

Hazard identification No.

UN number

Classification code

Safety signs



C1

8



Tunnel restriction code

(E)

Air transport - ICAO/IATA

Packaging instructions passenger

852

Cargo packaging instructions

856

Marine transport - IMDG

EmS (emergency plan)

F-A, S-B

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16th December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No. 1907/2006, as amended. 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 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

15.2. Chemical safety assessment

not available

SECTION 16: Other information**A list of standard risk phrases used in the safety data sheet**

H290	May be corrosive to metals.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Guidelines for safe handling used in the safety data sheet

P280	Wear protective gloves/protective clothing/eye 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.
P337+P313	If eye irritation persists: Get medical advice/attention.

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Other important information about human health protection

The product must not be - unless specifically approved by the manufacturer/importer - used for purposes other than as per the Section 1. The user is responsible for adherence to all related health protection regulations.

Key to abbreviations and acronyms used in the safety data sheet

ADR	European agreement concerning the international carriage of dangerous goods by road
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures
EC	Identification code for each substance listed in EINECS
EC ₅₀	Concentration of a substance when it is affected 50% of the population
EINECS	European Inventory of Existing Commercial Chemical Substances
EmS	Emergency plan
EU	European Union
EuPCS	European Product Categorisation System
IATA	International Air Transport Association
IBC	International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
INCI	International Nomenclature of Cosmetic Ingredients
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC ₅₀	Lethal concentration of a substance in which it can be expected death of 50% of the population
log K _{ow}	Octanol-water partition coefficient
NPK	Maximum admissible concentration
OEL	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative and Toxic
PEL	Permissible Exposure Limit
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Agreement on the transport of dangerous goods by rail
UN	Four-figure identification number of the substance or article taken from the UN Model Regulations
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials
VOC	Volatile organic compounds
vPvB	Very Persistent and very Bioaccumulative
Acute Tox.	Acute toxicity
Aquatic Acute	Hazardous to the aquatic environment
Aquatic Chronic	Hazardous to the aquatic environment (chronic)
Eye Dam.	Serious eye damage
Met. Corr.	Corrosive to metals
Skin Corr.	Skin corrosion
STOT SE	Specific target organ toxicity - single exposure

Training guidelines

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

Recommended restrictions of use

not available

Information about data sources used to compile the Safety Data Sheet

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REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended.
REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Data from
the manufacturer of the substance / mixture, if available - information from registration dossiers.

The changes (which information has been added, deleted or modified)

The version 4.0 replaces the SDS version from 13 January 2023. Changes were made in sections 2, 15 and 16.

Statement

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.