

Safety data sheet

according to Regulation (EC) No 1907/2006



Trade name: **TarClean**
Issue/Revision: 04.01.2024

Version: 3.0
Replaces version: 2.01

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name: **TarClean**
UFI: W605-F1D6-000U-UN4U

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

Relevant identified uses: Cleaning agent
Intended purpose: Liquid concentrate for the cleaning and self-acting removal of acid-soluble deposits (e. g. tartar and cement residues) from medical devices such as dental prostheses and instruments.
Uses advised against: None at intended use.
Note: The product is intended for professional users.

1.3. Details of the supplier of the safety data sheet

Manufacturer/Supplier: ALPRO MEDICAL GMBH
Mooswiesenstraße 9
D-78112 St. Georgen (Germany)
Telephone: +49 7725 9392-0
Telefax: +49 7725 9392-91
E-mail: info@alpro-medical.de
Internet: www.alpro-medical.de

E-mail address for the competent person responsible for the safety data sheet: doku@alpro-medical.de

1.4. Emergency telephone number

In-house emergency telephone number: +49 7725 9392-0
Monday – Friday from 08:00 am to 04:30 pm (UTC+1);
for chemical information and legal information on hazardous substances only
Poison centre: +49 761 19240
Poisoning information centre, Freiburg, Germany
(24 h / 7 d), English is spoken
National Poisons Information Service (UK): +44 344 892 0111
National Poisons Information Service (NPIS)
(24 h / 7 d), Medical Professionals Only

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification in accordance with Regulation (EC) No 1272/2008 [CLP]

Classification	Classification procedure
Skin Corr. 1B; H314	Calculation method

Full text of hazard classes as well as H-phrases: see under SECTION 16.1.

2.2. Label elements

Label elements in accordance with Regulation (EC) No 1272/2008 [CLP]

Hazard pictograms:



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Signal word:	Danger
Hazard components for labelling:	Phosphoric acid, monomethyl ester (812-00-0); 1 - 5 % phosphoric acid (7664-38-2)
H-phrases:	H314 Causes severe skin burns and eye damage.
P-phrases:	P280 Wear protective gloves/protective clothing/eye protection/face protection.
	P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
	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/ doctor.

2.3. Other hazards

The substances in the mixture do not meet the PBT/vPvB criteria according to Regulation (EC) No 1907/2006, Annex XIII (see SECTION 12.5.).

The substances in the mixture have no endocrine disrupting properties according to Regulation (EC) No 1907/2006, Annex XIV (see SECTION 11 and SECTION 12.6.). They are not on the list of substances of very high concern for authorisation according to Regulation (EC) No 1907/2006, Article 59, paragraph 10).

No further hazards known.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

Chemical characterisation: Mixture of substances listed below with non-hazardous additions in aqueous solution.

Hazardous ingredients

<i>Chemical name</i>	<i>Identification numbers</i>	<i>Classification in accordance with Regulation (EC) No 1272/2008</i>	<i>Weight %</i>
Phosphoric acid, monomethyl ester	CAS No: 812-00-0 EC No: 212-379-1	Skin Corr. 1B; H314	≥ 5 - < 15
Butane-1,4-diol	CAS No: 110-63-4 EC No: 203-786-5 REACH Registration No: 01-2119471849-20-XXXX	Acute Tox. 4; H302 STOT SE 3; H336	≥ 1 - < 5
Phosphoric acid ...%	CAS No: 7664-38-2 EC No: 231-633-2 Index No: 015-011-00-6 REACH Registration No: 01-2119485924-24-XXXX	Met. Corr. 1 ; H290 Acute Tox. 4; H302 Skin Corr. 1B; H314 Eye Dam. 1; H318 Skin Irrit. 2; H315 Eye Irrit. 2; H319 <i>Specific concentration limits:</i> <i>Skin Corr. 1B; H314: C ≥ 25 %</i> <i>Skin Irrit. 2; H315: 10 % ≤ C < 25 %</i> <i>Eye Irrit. 2; H319: 10 % ≤ C < 25 %</i>	≥ 1 - < 5

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2-(2-Butoxyethoxy) ethanol	CAS No: 112-34-5 EC No: 203-961-6 Index No: 603-096-00-8 REACH Registration No: 01-2119475104-44-XXXX	Eye Irrit. 2; H319	≥ 1 - < 5
Fatty alcohol polyglycol ether	CAS No: 68439-49-6 EC No: 500-212-8	Eye Irrit. 2; H319	≥ 0.5 - < 2

Full text of hazard classes and H-phrases: see under SECTION 16.1.
Occupational exposure limits: see SECTION 8.1.

SECTION 4: First aid measures

4.1. Description of first aid measures

- General information: First aider: Pay attention to self-protection!
Remove contaminated, saturated clothing immediately.
- Following inhalation: Move affected person into fresh air and keep still and warm. Seek medical advice.
- Following skin contact: Wash skin immediately with plenty of water and soap. In case of skin reactions, consult a physician.
- Following eye contact: Flush eyes immediately with flowing water for 10 to 15 minutes holding eyelids apart. Remove contact lenses, if present and easy to do. Consult an ophthalmologist.
- Following ingestion: Rinse mouth with water. Let drink plenty of water. Do not induce vomiting (risk of perforation). Consult a physician immediately.

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

Causes severe skin burns and eye damage.

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

No information available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: Water spray jet, alcohol resistant foam, extinguishing powder, carbon dioxide (CO₂)

Unsuitable extinguishing media: Full water jet

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products: Carbon monoxide (CO), carbon dioxide (CO₂), phosphorus oxides (P_xO_y)

5.3. Advice for firefighters

Special protective equipment: Wear self-contained breathing apparatus.

Further information: Cool endangered containers with water spray jet. Collect contaminated fire extinguishing water separately. Do not discharge into drains or rivers.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Use personal protective equipment. See SECTION 8.2.

Avoid skin and eye contact. Special danger of slipping by leaked/spilled product. Evacuate danger area. Observe emergency plans. Consult experts.

For emergency responders

Use personal protective equipment. See SECTION 8.2.

6.2. Environmental precautions

Do not discharge into drains or surface and ground water.

6.3. Methods and material for containment and cleaning up

Containment

For large spills, dyke spilled material or otherwise contain material to ensure runoff does not reach a waterway. Cover or seal drains.

Cleaning up

Wipe up small amounts with absorbent material (e.g. cloth, fleece). Absorb large amounts with liquid-binding material (sand, diatomaceous earth, universal binder, sawdust). Collect in suitable, closed containers for disposal. Clean contaminated surfaces thoroughly.

Other information

Inappropriate containment and cleaning methods are not known.

6.4. Reference to other sections

Information on safe handling see SECTION 7.1.

Information on personal protective equipment see SECTION 8.2.

Information on disposal see SECTION 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions

Avoid contact with skin and eyes.

Do not mix with alkaline solutions or other cleaners or disinfectants.

Advice on general occupational hygiene

When using do not eat, drink or smoke. Wash hands before breaks and at end of work. Keep away from medicines, food, feed, cosmetics and stimulants.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels: Keep only in the original container. Keep container tightly closed and kept upright to prevent any leakage.

Advice on common storage: Keep away from food, drink and animal feedingstuffs.

Further information on storage conditions: Do not store below -5°C.

7.3. Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific end uses are stipulated.

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Industry and sector specific guidance

- [DE] TRGS 525 – Hazardous substances in medical care facilities (Section 7 Activities with disinfectants); Issue: September 2014;
Source: GMBI 2014 page 1294-1307 of 13.10.2014 [No 63]; 10.07.2015 [No 27]; www.baua.de
- [DE] DGUV rules 207-206 – Prevention of chemical risks when handling disinfectants in health service, Issue: 2016.12; source: www.dguv.de/publikationen

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

Country	Limit values				Legal basis	Remarks
	Long term (8 hours)		Short term (15 minutes)			
	ppm	mg/m ³	ppm	mg/m ³		
Phosphoric acid (CAS No: 7664-38-2)						
EU		1		2	2000/39/EC	
UK		1		2	EH40	
2-(2-Butoxyethoxy) ethanol (CAS No: 112-34-5)						
EU	10	67.5	15	101.2	2006/15/EC	
UK	10	67.5	15	101.2	EH40	
Butan-1,4-diol (CAS-Nr.: 110-63-4)						
EU						no limit value specified
UK					EH40	no limit value specified

Used abbreviations, symbols, numerals and explanations

-

Biological limit values

Does not contain substances above concentration limits fixing a biological limit value.

Information on monitoring procedures

BS EN 482:2021-04; Title: Workplace exposure - Procedures for the determination of the concentration of chemical agents;
British version of EN 482:2021

BS EN 689:2018; Title: Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy;
British version of EN 689:2018

BS EN 14042:2003-04-24; Title: Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents;
British version of EN 14042:2003)

CEN/TR 17055:2017; Title: Workplace exposure. Measurement of chemical agents complying with the requirements given in EN 482 and either one of EN 838, EN 1076, EN 13205, EN 13890 and EN 13936.
Choice of procedures

ISO TR 14294:2011; Title: Workplace atmospheres. Measurement of dermal Exposure. Principles and methods

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8.2. Exposure controls

Appropriate engineering controls

Technical and organisational protective measures

The eyewash station (or eyewash bottle) and emergency shower must be located near the workplace.

Personal protective equipment

Eye/face protection:	Safety glasses with side protection according to BS EN 166
Skin protection:	Protective gloves according to EN 374-1 and EN 21420
Hand protection:	<u>Splash guard:</u> Protective gloves: type C; permeation-resistant at least 10 minutes <u>Permanent contact (> 480 min):</u> Protective gloves: type A or B; code letters: A, S, G; permeation-resistant at least 30 minutes
Other skin protection:	Long-sleeved protective clothing (lab coat)
Respiratory protection:	Not necessary when used as intended.
Thermal hazards:	No special protective measures necessary.

Environmental exposure controls

Do not discharge into drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance/physical state:	clear, pink liquid
Odour:	of mint
Odour threshold:	no data available
Melting point/freezing point:	no data available
Initial boiling point and boiling range:	no data available
Flammability:	not applicable
Lower explosive limit:	not applicable
Upper explosive limit:	not applicable
Flash point:	not applicable
Auto-ignition temperature:	no data available
pH (undiluted):	< 1 (20 °C)
Kinematic viscosity:	no data available
Solubility in water:	completely soluble
Partition coefficient: n-octanol/water	not applicable
Vapour pressure:	no data available (... °C)
Density:	1.040 – 1.050 g/cm ³ (20 °C)
Relative vapour density:	no data available
Particle characteristics:	not applicable

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9.2. Other information

9.2.1. Information with regard to physical hazard classes

Explosive substances/mixtures and products containing explosives:	not applicable
Flammable gases:	not applicable
Aerosols:	not applicable
Oxidising gases:	not applicable
Gases under pressure:	not applicable
Flammable liquids:	not applicable
Flammable solids:	not applicable
Self-reactive substances and mixtures:	not applicable
Pyrophoric liquids:	not applicable
Pyrophoric solids:	not applicable
Self-heating substances and mixtures:	not applicable
Substances and mixtures, which emit flammable gases in contact with water:	not applicable
Oxidising liquids:	not applicable
Oxidising solids:	not applicable
Organic peroxides:	not applicable
Substances and mixtures corrosive to metals:	not applicable
Desensitised explosives:	not applicable

9.2.2. Other safety characteristics

Electrical conductivity (undiluted): 50 - 60 mS/cm (20 °C)

SECTION 10: Stability and reactivity

10.1. Reactivity

Reacts with alkalis.

10.2. Chemical stability

The product is stable when handled and stored as intended.

10.3. Possibility of hazardous reactions

Reacts with alkalis.

10.4. Conditions to avoid

None known

10.5. Incompatible materials

Laser markings and colored instruments can fade.

10.6. Hazardous decomposition products

Does not decompose when used as intended.

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Product

Acute toxicity - oral:	Acute Toxicity Estimate ATE _{mix} > 2000 mg/kg => no classification
Acute toxicity - dermal:	Acute Toxicity Estimate ATE _{mix} > 2000 mg/kg => no classification
Acute toxicity - inhalation:	Acute Toxicity Estimate ATE _{mix} > 20 mg/l => no classification

Ingredients

Butane-1,4-diol (CAS No: 110-63-4):

Acute toxicity - oral: LD₅₀: 1500 mg/kg; species: rat; method: BASF-test

Skin corrosion/irritation

Product

Causes severe skin burns. [calculation method]

Serious eye damage/irritation

Product

Causes serious eye damage. [calculation method]

Respiratory or skin sensitisation

Product

No data available.

Germ cell mutagenicity

Product

No data available.

Carcinogenicity

Product

No data available.

Reproductive toxicity

Product

No data available.

STOT-single exposure

Product

No classification. [calculation method]

Ingredients

Butane-1,4-diol (CAS No: 110-63-4):

May cause drowsiness or dizziness.

STOT-repeated exposure

Product

No data available.

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Aspiration hazard

Product

No data available.

Information on other hazards

Endocrine disrupting properties:

No substances are contained that have endocrine disrupting properties for humans.

SECTION 12: Ecological information

12.1. Toxicity

No data available.

12.2. Persistence and degradability

Biodegradability:

The product is biodegradable according to OECD criteria. The statement has been derived from the properties of the organic ingredients.

Phosphoric acid and derivatives of phosphoric acid as inorganic substances are not subject to biodegradation. At normal dilution they do not endanger the function of a biological wastewater treatment plant and they will be eliminated for example in a phosphate precipitation stage.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to Regulation (EC) No 1907/2006, Annex XIII.

12.6. Endocrine disrupting properties

No substances are contained that have endocrine disrupting properties for non-target organisms.

12.7. Other adverse effects

No data available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal of the product

Product residues must be disposed of as hazardous waste in compliance with the Directive 2008/98/EC on waste as well as national and regional regulations. Do not dispose of via the waste water. Leave product in the original container as possible. Do not mix with other waste materials.

Waste codes / waste designations according to EWC

Product residues: 16 10 03* aqueous concentrates containing hazardous substances

Disposal of the packaging

Packaging contaminated with product is considered as hazardous waste and must be disposed of accordingly.

Waste codes / waste designations according to EWC

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

Recommendation

Contaminated packaging must be emptied optimally and can be recycled after appropriate cleaning (rinse with water).

From a dilution to 10 % the mixture is no longer classified as a hazardous substance.

SECTION 14: Transport information

14.0. Transport classification

Dangerous good in sense of the transport regulations in road traffic (ADR), railway traffic (RID), inland waterway traffic (ADN), maritime traffic (IMDG-Code) and air traffic (ICAO-TI/IATA-DGR).

14.1. UN number

UN 1760

14.2. UN proper shipping name

ADR/RID/ADN

CORROSIVE LIQUID, N.O.S. (Phosphoric acid monomethylester, Phosphoric acid)

IMDG-Code/ICAO-TI/IATA-DGR

CORROSIVE LIQUID, N.O.S. (Phosphoric acid monomethylester, Phosphoric acid)

14.3. Transport hazard class(es)

Class: 8

Subsidiary risk(s): -

14.4. Packing group

III

14.5. Environmental hazards

ADR/RID/ADN

Environmentally Hazardous: No

IMDG-Code

Marine Pollutant: No

14.6. Special precautions for user

Not necessary.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

14.8. Further information

Transport category according to ADR section 1.1.3.6: 3

Maximum total quantity per transport unit according to ADR section 1.1.3.6: 1000 L

Limited quantity (Maximum quantity per inner packaging) according to ADR/RID/ADN/IMDG-Code: 5 L

Classification code according to ADR/RID/ADN: C9

Hazard identification number according to ADR/RID: 80

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Tunnel restriction code according to ADR/RID:	E
Segregation group according to IMDG-Code section 5.4.1.5.11.1:	IMDG-Code- Segregation group 1 – acids
EmS codes:	F-A, S-B

SECTION 15: Regulatory information

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

EU-Regulations

REGULATION (EC) No 1005/2009 on substances that deplete the ozone layer
not applicable

REGULATION (EC) No 2019/1021 on persistent organic pollutants
not applicable

REGULATION (EU) No 649/2012 concerning the export and import of hazardous chemicals
not applicable

REGULATION (EU) No 648/2004 on detergents

Phosphates: $\geq 5 - \leq 15$
Anionic surfactants: $< 5 \%$
Non-ionic surfactants: $< 5 \%$

DIRECTIVE 2012/18/EU (Seveso III Directive) on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC
not applicable

DIRECTIVE 2010/75/EU on industrial emissions (integrated pollution prevention and control)
VOC-Gehalt: $< 3 \%$

REACH – List of substances subject to authorisation (Annex XIV)
not applicable

REACH – Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)
not applicable

COUNCIL DIRECTIVE 94/33/EC on the protection of young people at work
Observe employment restrictions for juveniles.

COUNCIL DIRECTIVE 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding
not applicable

15.2. Chemical safety assessment

For this mixture no chemical safety assessment has been carried out.

SECTION 16: Other information

16.1. Full text of hazard classes as well as H-phrases

Hazard classes

Acute Tox. Acute toxicity

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Eye Irrit.	Eye irritation
Skin Corr.	Skin corrosion
Skin Irrit.	Skin irritation
STOT SE	Specific target organ toxicity (single exposure)

H-phrases (Hazard statements)

H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.

16.2. Abbreviations and acronyms

ADN	<u>A</u> ccord européen relatif au transport international des marchandises <u>d</u> angereuses par voie de <u>n</u> avigation intérieure (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	<u>A</u> ccord européen relatif au transport international des marchandises <u>d</u> angereuses par <u>r</u> oute (European Agreement concerning the International Carriage of Dangerous Goods by Road)
BS	<u>B</u> ritish <u>S</u> tandards
CAS	<u>C</u> hemical <u>A</u> bstracts <u>S</u> ervice
CLP	Regulation on <u>C</u> lassification, <u>L</u> abelling and <u>P</u> ackaging of Substances and Mixtures
[DE]	National German regulations
DGUU	<u>D</u> eutsche <u>G</u> esetzliche <u>U</u> nfall <u>v</u> ersicherung (English: German statutory accident insurance)
EC	<u>E</u> uropean <u>C</u> ommunity
EEC	<u>E</u> uropean <u>E</u> conomic <u>C</u> ommunity
EN	European Standard
EU	<u>E</u> uropean <u>U</u> nion
EWC	<u>E</u> uropean <u>W</u> aste <u>C</u> atalogue
GMBI	<u>G</u> emeinsames <u>M</u> inisterial <u>b</u> latt (English: Joint Ministerial Gazette)
IATA-DGR	<u>I</u> nternational <u>A</u> ir <u>T</u> ransport <u>A</u> ssociation - <u>D</u> angerous <u>G</u> oods <u>R</u> egulations
ICAO-TI	Technical Instructions For The Safe Transport of Dangerous Goods by Air
IMDG-Code	<u>I</u> nternational <u>M</u> aritime Code for <u>D</u> angerous <u>G</u> oods
LC ₅₀	Median lethal concentration
LD ₅₀	Median lethal dose
N. O. S.	Not otherwise specified
NOAEL	No observed adverse effect level
OECD	<u>O</u> rganization for <u>E</u> conomic <u>C</u> o-operation and <u>D</u> evelopment
PBT	<u>P</u> ersistent, <u>b</u> ioaccumulative and <u>t</u> oxic
ppm	<u>P</u> arts <u>p</u> er <u>m</u> illion
REACH	<u>R</u> egistration, <u>E</u> valuation, <u>A</u> uthorisation and Restriction of <u>C</u> hemicals
RID	<u>R</u> èglement concernant le transport <u>I</u> nternational ferroviaire de marchandises <u>D</u> angereuses (Regulations Concerning the International Carriage of Dangerous Goods by Rail)
TRGS	<u>T</u> echnische <u>R</u> egeln für <u>G</u> efahr <u>s</u> toffe (English: Technical Rules for Hazardous Substances)
UN	<u>U</u> nited <u>N</u> ations
UTC	Coordinated Universal Time (French: Temps Universel Coordonné)
VOC	Volatile Organic Compounds
vPvB	<u>V</u> ery persistent and <u>v</u> ery <u>b</u> ioaccumulative

16.3. Key literature references and sources for data

- Regulation (EC) No 1907/2006 (REACH), Annex II

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- European Chemicals Agency (ECHA) – Guidance on the compilation of safety data sheets; Version 4.0 (December 2022); <https://echa.europa.eu/documents>
- Regulation (EC) No 1272/2008 (CLP regulation)
- European Chemicals Agency (ECHA) – Guidance on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008; Version 4.2 (03/2021); <https://echa.europa.eu/documents>
- European Chemicals Agency (ECHA), Registered substances; <https://echa.europa.eu/information-on-chemicals/registered-substances>
- European Chemicals Agency (ECHA), C&L Classification and Labelling Inventory; <https://echa.europa.eu/information-on-chemicals/cl-inventory-database>
- Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA): GESTIS database on hazardous substances and GESTIS - International limit values for chemical agents; <https://www.dguv.de/ifa/index.jsp>
- German Environmental Agency (Umweltbundesamt), Section IV 2.4: Office of Documentation and Information on Substances Hazardous to Waters RIGOLETTO (catalogue of Substances Hazardous to Waters); <https://webriigoletto.uba.de/rigoletto>

16.4. Methods according to Article 9 of Regulation (EC) No 1272/2008 for the evaluation of information for classification purposes

Calculation method according to the criteria in Annex I 1272/2008.
pH value measurement.
Material compatibility and corrosiveness in practical tests

16.5. Training advice

Provide adequate information, instructions and training for users.

16.6. Indication of changes

A dash in the left hand margin indicates an amendment from the previous version.

The information given in the safety data sheet only applies to the described product in connection with its intended use. This information is based on the latest state of our knowledge at the time of revision. In particular, it describes our product under the aspect of its hazards and safety measures to be taken. It does not constitute any guarantee of product properties and quality features.
