according to Regulation (EC) No 1907/2006



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

1.1. Product identifier

Trade name: AlproJet-DD

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

Relevant identified uses: Cleaning and disinfecting agent

Intended purpose: Liquid concentrate with enhanced disinfecting effect for

the daily cleaning and maintenance of dental aspiration

systems with and without amalgam separator.

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: alpro@alpro-medical.de
Internet: www.alpro-medical.com

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

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
STOT SE 3; H335	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:



according to Regulation (EC) No 1907/2006



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Signal word: Danger

Hazard components

for labelling: 2-Aminoethanol (141-43-5); Benzalkonium chloride (85409-22-9)

H-phrases: H314 Causes severe skin burns and eye damage.

H335 May cause respiratory irritation.

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.

No further hazards known.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

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

aqueous solution.

Hazardous ingredients

Chemical name	Identification numbers	Classification in accordance with	Weight %
		Regulation (EC) No 1272/2008	
2-Aminoethanol	CAS No: 141-43-5	Acute Tox. 4; H332	≥ 5 - < 15
	EC No: 205-483-3	Acute Tox. 4; H312	
	Index No: 603-030-00-8	Acute Tox. 4; H302	
	REACH Registration No:	Skin Corr. 1B; H314	
	01-2119486455-28-XXXX	STOT SE 3; H335	
		Specific concentration limits:	
		STOT SE 3; H335: C ≥ 5 %	
Trisodium	CAS No: 5064-31-3	Carc. 2; H351	≥1-<5
nitrilotriacetate	EC No: 225-768-6	Acute Tox. 4; H302	
	Index No: 607-620-00-6	Eye Irrit. 2; H319	
	REACH Registration No:	Specific concentration limits:	
	01-2119519239-36-XXXX	Carc. 2; H351: C ≥ 5 %	
Propan-2-ol	CAS No: 67-63-0	Flam. Liq. 2; H225	≥1-<5
	EC No: 200-661-7	Eye Irrit. 2; H319	
	Index No: 603-117-00-0	STOT SE 3; H336	
	REACH Registration No:		
	01-2119457558-25-XXXX		
Benzalkonium chloride	CAS No: 85409-22-9	Acute Tox. 4; H302	≥1-<5
	EC No: 287-089-1	Skin Corr. 1B; H314	
		Aquatic Acute 1; H400	

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Quaternary	CAS No: 63449-41-2	Acute Tox. 4; H312	< 0,2
ammonium	EC No: 264-151-6	Acute Tox. 4; H302	
compounds, benzyl-	Index No: 612-140-00-5	Skin Corr. 1B; H314	
C8-18-alkyldimethyl,		Aquatic Acute 1; H400	
chlorides			

Full text of hazard classes and H-phrases: see SECTION 16.1.

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. May cause respiratory irritation.

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), nitrogen oxides (NO_x),

hydrogen chloride (HCI)

5.3. Advice for firefighters

Special protective equipment: Wear self-contained breathing apparatus.

Further information: Cool endangered containers with water spray jet.

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.

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Avoid skin and eye contact. Do not breathe vapours. Provide adequate ventilation. 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 rivers.

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. Avoid breathing aerosols and vapours. Keep container tightly closed. Fill refill packages only in labelled original bottles.

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 food and drink.

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: Not necessary

Storage class ([DE] TRGS 510): LGK 8B Non-combustible corrosive hazardous substances

7.3. Specific end use(s)

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

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]; www.baua.de

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[DE] DGUV rules 107-002 (former BGR 206) - Disinfection works in health service

Issue: July 1999; Source: www.dguv.de/publikationen

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

		Limit	values				
Country	Country Long term (8 hours)		Short term (15 minutes)		Legal basis	Remarks	
	ppm	mg/m³	ppm	mg/m³			
2-Aminoetha	2-Aminoethanol (CAS No: 141-43-5)						
EU	1	2.5	3	7.6	2006/15/EC	Skin	
UK	1	2.5	3	7.6	EH40	Sk	
Propan-2-ol (CAS No: 67-63-0)							
EU						no limit value specified	
UK	400	999	500	1250	EH40		

Used abbreviations, symbols, numerals and explanations in column "Remarks"

Skin A significant uptake of the substance through the skin is possible.

Sk Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.

Biological limit values

Country	Parameter	Limit value	Test material	Sampling time	Legal basis
Propan-2-ol (CAS No: 67-63-0)					
	Acetone	25 mg/l	Whole	End of exposition, resp. end of shift	TRGS 903
Germany			blood		
	Acetone	25 mg/l	Urine	End of exposition, resp. end of shift	TRGS 903

Information on monitoring procedures

BS EN 482:2012-04-30; Title: Workplace exposure - General requirements for the performance of procedures for the measurement of chemical agents;

British version of EN 482:2012

BS EN 689:1996-04-15; 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 689:1995

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

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 EN 166

according to Regulation (EC) No 1907/2006



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Skin protection:

Hand protection: Protective gloves according to EN 374

Splash guard:

Disposable gloves made of nitrile rubber (thickness 0.11 mm)

Permanent contact (> 480 min):

Protective gloves made of nitrile rubber (thickness 0.40 mm)

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: clear, blue-green liquid

Odour: of lemon

Odour threshold: no data available

pH (20 g/l H_2O): 11.0 – 12.0 (20 °C)

Melting point/freezing point: no data available Initial boiling point and boiling range: no data available

Flash point: > 60 °C

Evaporation rate: no data available
Flammability (solid, gas): not applicable
Lower explosive limit: not applicable
Upper explosive limit: not applicable

Vapour pressure: no data available (... °C)

Vapour density: no data available

Relative density: 1.030 - 1.035 (20 °C)

Solubility in water: completely soluble Partition coefficient: not applicable

n-octanol/water

Auto-ignition temperature: not applicable

Decomposition temperature: no data available

Viscosity: no data available

Explosive properties: none Oxidising properties: none

9.2. Other information

Refractive index nD: 1.3638-1.3723 (20 °C) Electrical conductivity (20 g/l H_2O): 1500-2000 μ S/cm (20 °C)

according to Regulation (EC) No 1907/2006



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SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reactions when handled and stored as intended.

10.2. Chemical stability

The product is stable when handled and stored as intended.

10.3. Possibility of hazardous reactions

None known

10.4. Conditions to avoid

None known

10.5. Incompatible materials

None known

10.6. Hazardous decomposition products

Does not decompose when used as intended.

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 $ATE_{mix} > 2000 \text{ mg/kg}$

=> no classification

Acute toxicity - inhalation: Acute Toxicity Estimate $ATE_{mix} > 20 \text{ mg/l}$

=> no classification

Ingredients

2-Aminoethanol (CAS No: 141-43-5):

Acute toxicity - oral: LD₅₀: 1515 mg/kg; species: rat; method: OECD 401

Acute toxicity - inhalation: LC₅₀: > 1.3 mg/l; species: rat; 6 h; vapour

Trisodium nitrilotriacetate (CAS No: 5064-31-3):

Acute toxicity - oral: LD₅₀: 1000 - 2000 mg/kg; species: rat; method: (BASF-test)

Benzalkonium chloride (CAS No: 85409-22-9):

Acute toxicity - oral: LD₅₀: approx. 344 mg/kg; species: rat

Quaternary ammonium compounds, benzyl-C8-18-alkyldimethyl, chlorides (CAS No: 63449-41-2):

Acute toxicity - oral: LD₅₀: approx. 398 mg/kg; species: rat Acute toxicity - dermal: LD₅₀: 1420 mg/kg; species: rat

Skin corrosion/irritation

Product

Causes severe skin burns. [calculation method]

according to Regulation (EC) No 1907/2006



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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 classification. [calculation method]

Ingredients

Trisodium nitrilotriacetate (CAS No: 5064-31-3):

The substance was shown to have a carcinogenic effect in animal studies with long-term administration of large amounts via the drinking water or via the food. With single or short-term intake of the substance a carcinogenic effect is however practically ruled out.

Reproductive toxicity

Product

No data available.

STOT-single exposure

Product

May cause respiratory irritation. [calculation method]

Ingredients

2-Aminoethanol (CAS No: 141-43-5):

May cause respiratory irritation.

Propan-2-ol (CAS No: 67-63-0):

May cause drowsiness or dizziness.

STOT-repeated exposure

Product

No data available.

Aspiration hazard

Product

No data available.

SECTION 12: Ecological information

12.1. Toxicity

No classification. [calculation method]

according to Regulation (EC) No 1907/2006



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12.2. Persistence and degradability

Biodegradability:

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

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. 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

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).

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 1903

according to Regulation (EC) No 1907/2006



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14.2. UN proper shipping name

ADR/RID/ADN

DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Ethanolamine, Benzalkonium chloride)

IMDG-Code/ICAO-TI/IATA-DGR

DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Ethanolamine, Benzalkonium chloride)

14.3. Transport hazard class(es)

Class: 8

14.4. Packing group

Ш

14.5. Environmental hazards

Subsidiary risk(s):

ADR/RID/ADN

Environmentally Hazardous: No

IMDG-Code

Marine Pollutant: No

14.6. Special precautions for user

Not necessary.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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

Tunnel restriction code according to ADR/RID: Segregation group according to IMDG-Code

section 5.4.1.5.11.1: IMDG-Code- Segregation group 18 – alkalis

Ε

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

according to Regulation (EC) No 1907/2006



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REGULATION (EC) No 850/2004 on persistent organic pollutants and amending Directive 79/117/EEC not applicable

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

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)

not applicable

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

Observe employment restrictions for pregnant and nursing mothers.

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 and H-phrases

Hazard classes

Acute Tox. Acute toxicity
Aquatic Acute Acute aquatic hazard
Carc. Carcinogenicity
Eye Irrit. Eye irritation
Flam. Liq. Flammable liquid
Skin Corr. Skin corrosion

STOT SE Specific target organ toxicity (single exposure)

H-phrases (Hazard statements)

H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled

according to Regulation (EC) No 1907/2006



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H335 May cause respiratory irritation.H336 May cause drowsiness or dizziness.

H351 Suspected of causing cancer < state route of exposure if it is conclusively proven that

no other routes of exposure cause the hazard>.

H400 Very toxic to aquatic life.

16.2. Abbreviations and acronyms

ADN <u>A</u>ccord européen relatif au transport international des marchandises <u>d</u>angereuses par voie de

navigation intérieure (European Agreement concerning the International Carriage of

Dangerous Goods by Inland Waterways)

ADR Accord européen relatif au transport international des marchandises dangereuses par route

(European Agreement concerning the International Carriage of Dangerous Goods by Road)

BGR Berufsgenossenschaftliche Regeln (English: Employers' liability insurance association rules)

BS <u>British Standards</u>

CAS <u>Chemical Abstracts Service</u>

CLP Regulation on Classification, Labelling and Packaging of Substances and Mixtures

[DE] National German regulations

DGUV <u>Deutsche Gesetzliche Unfallversicherung</u> (English: German statutory accident insurance)

EC <u>European Community</u>

EEC European Economic Community

EmS <u>Em</u>ergency <u>S</u>chedules (Emergency response procedures for ships carrying dangerous goods)

EN European Standard
EU European Union

EWC <u>European Waste Catalogue</u>

GHS Globally Harmonized System of Classification, Labelling and Packaging of Chemicals

GMBl <u>G</u>emeinsames <u>M</u>inisterial<u>bl</u>att (English: Joint Ministerial Gazette)

IATA-DGR <u>International Air Transport Association - Dangerous Goods Regulations</u>

IBC-Code International Code for the Construction and Equipment of Ships carrying Dangerous

Chemicals in Bulk

ICAO-TI Technical Instructions For The Safe Transport of Dangerous Goods by Air

IMDG-Code International Maritime Code for Dangerous Goods

LC₅₀ Median lethal concentration

LD₅₀ Median lethal dose

LGK <u>Lagerklasse</u> (English: Storage class)

MARPOL International Convention for the Prevention of Marine Pollution from Ships

N.O.S. Not otherwise specified

NOAEL No Observed Adverse Effect Level (dose at which no adverse effect is found)

OECD <u>Organization for Economic Co-operation and Development</u>

PBT <u>Persistent, bioaccumulative and toxic</u>

ppm Parts per million

REACH <u>Registration</u>, <u>Evaluation</u>, <u>Authorisation</u> and Restriction of <u>Chemicals</u>

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>Technische Regeln für Gefahrstoffe</u> (English: Technical Rules for Hazardous Substances)

UN <u>U</u>nited <u>N</u>ations

UTC Coordinated Universal Time (French: Temps Universel Coordonné)

vPvB <u>Very persistent and very bioaccumulative</u>

16.3. Key literature references and sources for data

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

- European Chemicals Agency (ECHA) – Guidance on the compilation of safety data sheets; Version 2.1 (February 2014); http://echa.europa.eu/documents/10162/13643/sds_en.pdf

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- GISBAU (Hazardous substances information system of the BG BAU) course "safety data sheet"; http://www.bgbau.de/gisbau/SDB/lehrgang/lehrgang.htm
- Regulation (EC) No 1272/2008 (CLP regulation)
- European Chemicals Agency (ECHA) Guidance on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008 (04/2011);
 - http://echa.europa.eu/documents/10162/13562/clp labelling en.pdf
- European Chemicals Agency (ECHA), Registered substances; http://echa.europa.eu/information-on-chemicals/registered-substances
- European Chemicals Agency (ECHA), C&L Classification and Labelling Inventory; http://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;
 http://www.dguv.de/dguv/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); http://webrigoletto.uba.de/rigoletto

16.4. Training advice

Provide adequate information, instructions and training for users.

16.5. Indication of changes

A backslash 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.