

Safety data sheet

according to Regulation (EC) No 1907/2006



Trade name: **AlproJet-D**

Issue/Revision: 18.01.2021

Print date: 19.01.2021

Version: 2.1

Replaces version: 2.0

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

1.1. Product identifier

Trade name: **AlproJet-D**

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 for daily disinfection and simultaneous cleaning 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]

<i>Classification</i>	<i>Classification procedure</i>
Skin Irrit. 2; H315	Calculation method
Eye Dam. 1; H318	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:



Signal word: **Danger**

Safety data sheet

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Trade name: **AlproJet-D**

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Hazard components for labelling:		2-Aminoethanol (141-43-5); Benzalkonium chloride (85409-22-9)
H-phrases:	H315 H318	Causes skin irritation. Causes serious eye damage.
P-phrases:	P280 P305+P351+P338 P310	Wear protective gloves/eye protection/face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. 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 Regulation (EC) No 1272/2008	Weight %
2-Aminoethanol	CAS No: 141-43-5 EC No: 205-483-3 Index No: 603-030-00-8 REACH Registration No: 01-2119486455-28-XXXX	Acute Tox. 4; H332 Acute Tox. 4; H312 Acute Tox. 4; H302 Skin Corr. 1B; H314 STOT SE 3; H335 <i>Specific concentration limits</i> STOT SE 3; H335: C ≥ 5 %	≥ 1 - < 2.5
Trisodium nitrilotriacetate	CAS No: 5064-31-3 EC No: 225-768-6 Index No: 607-620-00-6 REACH Registration No: 01-2119519239-36-XXXX	Carc. 2; H351 Acute Tox. 4; H302 Eye Irrit. 2; H319 <i>Specific concentration limits</i> Carc. 2; H351: C ≥ 5 %	≥ 1 - < 2.5
Propan-2-ol	CAS No: 67-63-0 EC No: 200-661-7 Index No: 603-117-00-0 REACH Registration No: 01-2119457558-25-XXX	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336	≥ 1 - < 2.5
Benzalkonium chloride	CAS No: 85409-22-9 EC No: 287-089-1	Acute Tox. 4; H302 Skin Corr. 1B; H314 Aquatic Acute 1; H400	≥ 1 - < 2.5

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!

Safety data sheet

according to Regulation (EC) No 1907/2006



Trade name: **AlproJet-D**

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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. Consult a physician immediately.

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

Causes skin irritation. Causes serious 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), nitrogen oxides (NO_x), hydrogen chloride (HCl)

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.

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.

Safety data sheet

according to Regulation (EC) No 1907/2006



Trade name: **AlproJet-D**

Issue/Revision: 18.01.2021

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Replaces version: 2.0

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. 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: Not necessary

Further information on storage conditions: Not necessary

Storage class ([DE] TRGS 510): LGK 12 Non-combustible liquids that are not assigned to any of the aforementioned LGK

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

[DE] DGUV rules 107-002 (former BGR 206) - Disinfection works in health service
Issue: July 1999; Source: www.dguv.de/publikationen

Safety data sheet
according to Regulation (EC) No 1907/2006



Trade name: **AlproJet-D**
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 Print date: 19.01.2021

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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		
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)					
Germany	Acetone	25 mg/l	Whole blood	End of exposition, resp. end of shift	TRGS 903
	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) must be located near the workplace.

Personal protective equipment

Eye/face protection: Safety glasses with side protection according to EN 166

Safety data sheet

according to Regulation (EC) No 1907/2006



Trade name: **AlproJet-D**

Issue/Revision: 18.01.2021

Print date: 19.01.2021

Version: 2.1

Replaces version: 2.0

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: Not necessary when used as intended.

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 liquid	
Odour:	characteristic	
Odour threshold:	no data available	
pH (50 g/l H ₂ O):	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:	1.005 – 1.010	(20 °C)
Solubility in water:	completely soluble	
Partition coefficient: n-octanol/water	not applicable	
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 n _D :	1.3433 — 1.3463	(20 °C)
Electrical conductivity (50 g/l H ₂ O):	1400 – 1650 µS/cm	(20 °C)

Safety data sheet

according to Regulation (EC) No 1907/2006



Trade name: **AlproJet-D**

Issue/Revision: 18.01.2021

Print date: 19.01.2021

Version: 2.1

Replaces version: 2.0

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

Skin corrosion/irritation

Product

Causes skin irritation. [calculation method]

Serious eye damage/irritation

Product

Causes serious eye damage. [calculation method]

Safety data sheet
according to Regulation (EC) No 1907/2006



Trade name: **AlproJet-D**
Issue/Revision: 18.01.2021
Print date: 19.01.2021

Version: 2.1
Replaces version: 2.0

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

No classification. [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]

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.

Safety data sheet

according to Regulation (EC) No 1907/2006



Trade name: **AlproJet-D**

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Print date: 19.01.2021

Version: 2.1

Replaces version: 2.0

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

No 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

-

14.2. UN proper shipping name

-

14.3. Transport hazard class(es)

-

14.4. Packing group

-

Safety data sheet
according to Regulation (EC) No 1907/2006



Trade name: **AlproJet-D**
Issue/Revision: 18.01.2021
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Version: 2.1
Replaces version: 2.0

14.5. Environmental hazards

-

14.6. Special precautions for user

-

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

-

14.8. Further information

-

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 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
not applicable

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.

Safety data sheet

according to Regulation (EC) No 1907/2006



Trade name: **AlproJet-D**

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Replaces version: 2.0

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 Dam.	Serious eye damage
Eye Irrit.	Eye irritation
Flam. Liq.	Flammable liquid
Skin Corr.	Skin corrosion
Skin Irrit.	Skin irritation
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.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
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 <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)
BGR	<u>B</u> erufsgenossenschaftliche <u>R</u> egeln (English: Employers' liability insurance association rules)
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
DGUV	<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
GHS	<u>G</u> lobally <u>H</u> armonized <u>S</u> ystem of Classification, Labelling and Packaging of Chemicals
GMBI	<u>G</u> emeinsames <u>M</u> inisterial <u>bl</u> att (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
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 <u>M</u> aritime Code for <u>D</u> angerous <u>G</u> oods

Safety data sheet

according to Regulation (EC) No 1907/2006



Trade name: **AlproJet-D**

Issue/Revision: 18.01.2021

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Replaces version: 2.0

LC ₅₀	Median lethal concentration
LD ₅₀	Median lethal dose
LGK	<u>L</u> ager <u>k</u> lasse (English: Storage class)
MARPOL	International Convention for the Prevention of Marine Pollution from Ships
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 International 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)
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
- 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
- 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.
