

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

Trade name : Orotol® ultra Disinfection of suction systems
Revision : 02.01.2018
Print date : 02.01.2018

Version (Revision) : 2.0.1 (2.0.0)

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

1.1 Product identifier

Orotol® ultra Disinfection of suction systems

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

Relevant identified uses

Orotol® ultra is a highly effective aldehyde-free concentrate for the simultaneous disinfection, deodorization, cleaning and care of dental suction systems as well as spittoon bowls, being likewise suitable for all amalgam separators.

Product Categories [PC]

PC0 - Other
Disinfectants

Uses advised against

None, if handled according to order.

Remark

The product is intended for professional use.

1.3 Details of the supplier of the safety data sheet

Supplier (manufacturer/importer/only representative/downstream user/distributor)

orochemie GmbH + Co. KG

Street : Max-Planck-Straße 27

Postal code/city : 70806 Kornwestheim

Telephone : +49 7154 1308-0

Telefax : +49 7154 1308-40

Information contact : DÜRR DENTAL SE, Höpfigheimer Str. 17, 74321 Bietigheim-Bissingen, Germany

Tel: +49 7142 705-0, Fax: +49 7142 705-500, info@duerrdental.com

in Great Britain/Ireland:

DÜRR DENTAL [Products] UK Ltd., 14 Linnell Way - Telford Way Industrial Estate, Kettering Northants NN16 8PS, United Kingdom

Tel: +44 1536 526740, Fax.: +44 1536 526749, info@duerruk.com

1.4 Emergency telephone number

INT: +49 6132 84463 (24 h/7 d)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]

Eye Irrit. 2 ; H319 - Serious eye damage/eye irritation : Category 2 ; Causes serious eye irritation.

Classification procedure

The classification was carried out according to the calculation method of Regulation No. (EC) 1272/2008 [CLP] as well as in-house investigations.

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms



Exclamation mark (GHS07)

Signal word

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Warning

Hazard statements

H319 Causes serious eye irritation.

Precautionary statements

P235+P410 Keep cool. Protect from sunlight.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves and eye/face protection.

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

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

P501 Dispose of contents/container to hazardous or special waste collection point.

2.3 Other hazards

None

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description

Orotol® ultra contains sodium peroxocarbonate, alkaline cleaning agents, complexing agents, non-ionic surfactants, special antifoaming agents and auxiliary agents.

Hazardous ingredients

SODIUM CARBONATE PEROXYHYDRATE ; REACH registration No. : 01-2119457268-30 ; EC No. : 239-707-6; CAS No. : 15630-89-4

Weight fraction : $\geq 25 - < 30$ %

Classification 1272/2008 [CLP] : Ox. Sol. 2 ; H272 Eye Dam. 1 ; H318 Acute Tox. 4 ; H302

TETRASODIUM DIPHOSPHATE ; REACH registration No. : 01-2119489369-18 ; EC No. : 230-785-7; CAS No. : 7320-34-5

Weight fraction : $\geq 10 - < 15$ %

Classification 1272/2008 [CLP] : Eye Irrit. 2 ; H319

TRISODIUM ORTHOPHOSPHATE ; REACH registration No. : 01-2119489800-32 ; EC No. : 231-509-8; CAS No. : 7601-54-9

Weight fraction : $\geq 3 - < 8$ %

Classification 1272/2008 [CLP] : Skin Irrit. 2 ; H315 Eye Irrit. 2 ; H319 STOT SE 3 ; H335

FATTY ALCOHOL ALKOXYLATE ; REACH registration No. : 02-2119552554-37 ; CAS No. : 111905-53-4

Weight fraction : $\geq 1 - < 3$ %

Classification 1272/2008 [CLP] : Acute Tox. 4 ; H302 Eye Irrit. 2 ; H319 Aquatic Chronic 3 ; H412

Additional information

Full text of H- and EUH-phrases: see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information

Immediately remove all contaminated clothing. In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

Following inhalation

Provide fresh air. In case of respiratory tract irritation, consult a physician.

In case of skin contact

Wash with plenty of water. When in doubt or if symptoms are observed, get medical advice.

After eye contact

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

After ingestion

If swallowed, immediately drink: Water Never give anything by mouth to an unconscious person or a person with

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cramps. Do NOT induce vomiting. Call a physician immediately.

4.2 Most important symptoms and effects, both acute and delayed

Causes serious eye irritation.

4.3 Indication of any immediate medical attention and special treatment needed

None

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Extinguishing powder Water spray Water mist

Unsuitable extinguishing media

High power water jet

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products

Oxygen

5.3 Advice for firefighters

Cool endangered containers with water in case of fire.

Special protective equipment for firefighters

When extinguishing fires, use breathing apparatus with an independent source of air.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protection equipment. See protective measures under point 7 and 8.

For non-emergency personnel

Use personal protection equipment. See protective measures under point 7 and 8.

For emergency responders

Personal protection equipment

See protective measures under point 7 and 8.

6.2 Environmental precautions

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

6.3 Methods and material for containment and cleaning up

For cleaning up

Sweep up and place in clean, dry plastic containers; closure must not be air-tight. Avoid dust formation.

Other information

Treat the recovered material as prescribed in the section on waste disposal.

6.4 Reference to other sections

None

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Keep/Store only in original container. Please note safety instructions and directions for use on the drum. Handle and open container with care. Provide adequate ventilation. Avoid dust formation. Do not breathe dust.

Protective measures

Measures to prevent fire

When using do not smoke.

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7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep/Store only in original container. Do not store in temperatures exceeding 30 °C. Protect to direct exposure to the sun. Keep container tightly closed. Keep in a cool, well-ventilated place.

Hints on joint storage

Do not store together with flammable substances and acids. Store the foodstuffs separately.

7.3 Specific end use(s)

None

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

DNEL/DMEL and PNEC values

There are no data available on the preparation itself.

DNEL/DMEL

Limit value type :	DNEL Consumer (systemic) (TETRASODIUM DIPHOSPHATE ; CAS No. : 7320-34-5)
Exposure route :	Inhalation
Exposure frequency :	Long-term (repeated)
Limit value :	0,68 mg/l
Limit value type :	DNEL Consumer (systemic) (TETRASODIUM DIPHOSPHATE ; CAS No. : 7320-34-5)
Exposure route :	Oral
Exposure frequency :	Long-term (repeated)
Limit value :	> 70 mg/kg
Safety factor :	24 h
Limit value type :	DNEL Consumer (systemic) (TETRASODIUM DIPHOSPHATE ; CAS No. : 7320-34-5)
Exposure route :	Inhalation
Exposure frequency :	Long-term (repeated)
Limit value :	10,87 mg/m ³
Limit value type :	DNEL worker (systemic) (TETRASODIUM DIPHOSPHATE ; CAS No. : 7320-34-5)
Exposure route :	Inhalation
Exposure frequency :	Long-term (repeated)
Limit value :	2,79 mg/m ³
Limit value type :	DNEL worker (systemic) (TETRASODIUM DIPHOSPHATE ; CAS No. : 7320-34-5)
Exposure route :	Inhalation
Exposure frequency :	Long-term (repeated)
Limit value :	44,08 mg/m ³
Limit value type :	DNEL Consumer (systemic) (TRISODIUM ORTHOPHOSPHATE ; CAS No. : 7601-54-9)
Exposure route :	Inhalation
Exposure frequency :	Long-term (repeated)
Limit value :	3,04 mg/m ³
Limit value type :	DNEL worker (systemic) (TRISODIUM ORTHOPHOSPHATE ; CAS No. : 7601-54-9)
Exposure route :	Inhalation
Exposure frequency :	Long-term (repeated)
Limit value :	4,07 mg/m ³

PNEC

Limit value type :	PNEC aquatic, freshwater (TETRASODIUM DIPHOSPHATE ; CAS No. : 7320-34-5)
Limit value :	0,05 mg/l
Limit value type :	PNEC aquatic, intermittent release (TETRASODIUM DIPHOSPHATE ; CAS No. : 7320-34-5)
Limit value :	0,5 mg/l
Limit value type :	PNEC aquatic, marine water (TETRASODIUM DIPHOSPHATE ; CAS No. : 7320-34-5)
Limit value :	0,005 mg/l
Limit value type :	PNEC sewage treatment plant (STP) (TETRASODIUM DIPHOSPHATE ; CAS No. : 7320-34-5)

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Limit value : 50 mg/l
Limit value type : PNEC aquatic, freshwater (TRISODIUM ORTHOPHOSPHATE ; CAS No. : 7601-54-9)
Limit value : 0,05 mg/l
Limit value type : PNEC aquatic, intermittent release (TRISODIUM ORTHOPHOSPHATE ; CAS No. : 7601-54-9)
Limit value : 0,5 mg/l
Limit value type : PNEC aquatic, marine water (TRISODIUM ORTHOPHOSPHATE ; CAS No. : 7601-54-9)
Limit value : 0,005 mg/l
Limit value type : PNEC sewage treatment plant (STP) (TRISODIUM ORTHOPHOSPHATE ; CAS No. : 7601-54-9)
Limit value : 50 mg/l

8.2 Exposure controls

Personal protection equipment

Eye/face protection

Eye glasses with side protection DIN EN 166

Skin protection

Hand protection

Short-term exposure (Level 2: < 30 min): disposable gloves to EN374 category III, e.g. nitrile rubber, material thickness 0.1 mm.

Long-term exposure (Level 6: < 480 min): protective gloves to EN374 category III, e.g. nitrile rubber, material thickness 0.7 mm.

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits.

Body protection

Light protective clothing.

Respiratory protection

Usually no personal respiratory protection necessary.

General health and safety measures

Keep away from food, drink and animal feedingstuffs. Avoid contact with skin, eyes and clothes. Wash hands before breaks and after work. Separate storage of work clothes. When using do not eat, drink, smoke, sniff.

Occupational exposure controls

Technical measures to prevent exposure

Provide adequate ventilation.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : Powder

Colour : white

Odour : like Peppermint

Safety relevant basis data

Initial boiling point and boiling range :	(1013 hPa)		not applicable
Decomposition temperature :	(1013 hPa)	>	60 °C
Flash point :			not applicable
Ignition temperature :			not applicable
Lower explosion limit :			not applicable
Upper explosion limit :			not applicable
Vapour pressure :	(50 °C)		not applicable
Density :	(20 °C)		none
Bulk density :		approx.	920 kg/m ³
Solvent separation test :	(20 °C)		not applicable
pH value :	(20 °C / 10 g/l)		9 - 10

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log P O/W :		No data available	
Flow time :	(20 °C)	not applicable	DIN-cup 4 mm
Odour threshold :		not determined	
Maximum VOC content (EC) :		0,2	Wt %
Flammable solids :	Not applicable.		
Oxidising solids :	Not oxidizing.		
Explosive properties :	Not applicable.		
Corrosive to metals :	Not corrosive to metals.		

9.2 Other information

None

SECTION 10: Stability and reactivity

10.1 Reactivity

Thermal decomposition above approx. 60 °C (exothermal decomposition) combined with the liberation of oxygen.

10.2 Chemical stability

Stable under recommended storage and handling conditions (see section 7). Thermal decomposition above approx. 60 °C (exothermal decomposition) combined with the liberation of oxygen.

10.3 Possibility of hazardous reactions

Reactions with acids possible

10.4 Conditions to avoid

No information available.

10.5 Incompatible materials

Acids, heavy metals, decomposition catalysts.

10.6 Hazardous decomposition products

Oxygen

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute effects

Acute oral toxicity

Parameter :	LD50
Exposure route :	Oral
Species :	Rat
Effective dose :	> 2000 mg/kg
Method :	OECD 420
Parameter :	ATEmix calculated
Exposure route :	Oral
Effective dose :	2000 mg/kg
Parameter :	ATE (SODIUM CARBONATE PEROXYHYDRATE ; CAS No. : 15630-89-4)
Exposure route :	Oral
Effective dose :	500 mg/kg

Practical experience/human evidence

Causes serious eye irritation.

Acute dermal toxicity

Parameter :	ATEmix calculated
Exposure route :	Dermal
Effective dose :	not relevant
Parameter :	LD50 (SODIUM CARBONATE PEROXYHYDRATE ; CAS No. : 15630-89-4)
Exposure route :	Dermal
Species :	Rabbit
Effective dose :	> 2000 mg/kg

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Parameter : LD50 (TETRASODIUM DIPHOSPHATE ; CAS No. : 7320-34-5)
Exposure route : Dermal
Species : Rabbit
Effective dose : > 2000 mg/kg
Method : OECD 402
Parameter : LD50 (TETRASODIUM DIPHOSPHATE ; CAS No. : 7320-34-5)
Exposure route : Dermal
Species : Rabbit
Effective dose : > 4640 mg/kg
Parameter : LD50 (TRISODIUM ORTHOPHOSPHATE ; CAS No. : 7601-54-9)
Exposure route : Dermal
Species : Rat
Effective dose : > 2000 mg/kg
Parameter : LD50 (TRISODIUM ORTHOPHOSPHATE ; CAS No. : 7601-54-9)
Exposure route : Dermal
Species : Rabbit
Effective dose : > 300 mg/kg
Parameter : LD50 (TRISODIUM ORTHOPHOSPHATE ; CAS No. : 7601-54-9)
Exposure route : Dermal
Species : Rabbit
Effective dose : > 5000 mg/kg

Acute inhalation toxicity

Parameter : LC50 (TETRASODIUM DIPHOSPHATE ; CAS No. : 7320-34-5)
Exposure route : Inhalation
Species : Rat
Effective dose : > 1,1 mg/l
Method : OECD 403

Irritant and corrosive effects

Primary irritation to the skin

Not an irritant. Method : Human Skin Model (HSM) test

Irritation to eyes

Causes serious eye irritation. Method : OECD 437.

Sensitisation

No data available.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

No information available.

11.5 Additional information

The classification was carried out according to the calculation method of Regulation No. (EC) 1272/2008 [CLP] as well as in-house investigations.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity

Acute (short-term) fish toxicity

Parameter : LC0
Species : Poecilia reticulata (Guppy)
Evaluation parameter : Acute (short-term) fish toxicity
Effective dose : 24,4 mg/l
Exposure time : 96
Method : OECD 203
Parameter : EC50
Species : Poecilia reticulata (Guppy)
Evaluation parameter : Acute (short-term) fish toxicity

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Effective dose : 24,4 mg/l
Exposure time : 48 h
Method : OECD 203

Chronic (long-term) fish toxicity

Parameter : NOEC (SODIUM CARBONATE PEROXYHYDRATE ; CAS No. : 15630-89-4)
Species : Pimephales promelas (fathead minnow)
Evaluation parameter : Chronic (long-term) fish toxicity
Effective dose : 7,4 mg/l
Exposure time : 96 h

Parameter : NOEC (TETRASODIUM DIPHOSPHATE ; CAS No. : 7320-34-5)
Species : Oncorhynchus mykiss (Rainbow trout)
Evaluation parameter : Chronic (long-term) fish toxicity
Effective dose : 100 mg/l
Exposure time : 96 h
Method : OECD 203

Acute (short-term) daphnia toxicity

Parameter : EC50
Species : Daphnia magna (Big water flea)
Evaluation parameter : Acute (short-term) daphnia toxicity
Effective dose : 24,4 mg/l
Exposure time : 48 h
Method : OECD 202

Parameter : EC50
Species : Daphnia magna (Big water flea)
Evaluation parameter : Acute (short-term) daphnia toxicity
Effective dose : 32,4 mg/l
Exposure time : 24 h
Method : OECD 202

Parameter : EC0
Species : Daphnia magna (Big water flea)
Evaluation parameter : Acute (short-term) daphnia toxicity
Effective dose : 7,5 mg/l
Exposure time : 48 h
Method : OECD 202

Chronic (long-term) daphnia toxicity

Parameter : NOEC (SODIUM CARBONATE PEROXYHYDRATE ; CAS No. : 15630-89-4)
Species : Daphnia pulex (water flea)
Evaluation parameter : Chronic (long-term) daphnia toxicity
Effective dose : 2 mg/l
Exposure time : 48 h

Parameter : NOEC (FATTY ALCOHOL ALKOXYLATE ; CAS No. : 111905-53-4)
Species : Daphnia magna (Big water flea)
Evaluation parameter : Chronic (long-term) daphnia toxicity
Effective dose : > 0,1 - 1 mg/l

Acute (short-term) algae toxicity

Parameter : EC50
Species : Desmodesmus subspicatus
Evaluation parameter : Inhibition of growth rate
Effective dose : 29,9 mg/l
Exposure time : 72 h
Method : OECD 201

Parameter : EC0
Species : Desmodesmus subspicatus
Evaluation parameter : Inhibition of growth rate
Effective dose : 12,5 mg/l
Exposure time : 72 h

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Method : OECD 201

Chronic (long-term) algae toxicity

Parameter : NOEC (TETRASODIUM DIPHOSPHATE ; CAS No. : 7320-34-5)
Species : Algae
Evaluation parameter : Chronic (long-term) algae toxicity
Effective dose : > 100 mg/l
Exposure time : 72 h
Method : OECD 201

Bacteria toxicity

Parameter : Bacteria toxicity (FATTY ALCOHOL ALKOXYLATE ; CAS No. : 111905-53-4)
Species : Bacteria toxicity
Effective dose : > 1000 mg/l
Parameter : EC50 (TETRASODIUM DIPHOSPHATE ; CAS No. : 7320-34-5)
Evaluation parameter : Bacteria toxicity
Effective dose : > 1000 mg/l
Exposure time : 3 h

12.2 Persistence and degradability

Biodegradation

Readily biodegradable (according to OECD criteria). Method : OECD 301 D.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

Known or predicted distribution to environmental compartments

There are no data available on the preparation itself.

Adsorption/Desorption

12.5 Results of PBT and vPvB assessment

No information available.

12.6 Other adverse effects

No information available.

12.7 Additional ecotoxicological information

Do not allow to enter into surface water or drains.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product/Packaging disposal

Waste codes/waste designations according to EWC/AVV

Waste code product

Concentrate/larger quantities: 18 01 06* (disinfectant).

Waste treatment options

Appropriate disposal / Product

Dispose according to legislation. Consult the appropriate local waste disposal expert about waste disposal.

Appropriate disposal / Package

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

14.1 UN number

No dangerous good in sense of these transport regulations.

14.2 UN proper shipping name

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No dangerous good in sense of these transport regulations.

14.3 Transport hazard class(es)

No dangerous good in sense of these transport regulations.

14.4 Packing group

No dangerous good in sense of these transport regulations.

14.5 Environmental hazards

No dangerous good in sense of these transport regulations.

14.6 Special precautions for user

None

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

not applicable

SECTION 15: Regulatory information

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

National regulations

Restrictions of occupation

According to directive 94/33/EC, juveniles are only allowed to handle this product as long as all effects of dangerous substances are prevented.

15.2 Chemical safety assessment

For this mixture a chemical safety assessment has not been carried out.

SECTION 16: Other information

16.1 Indication of changes

02. Labelling according to Regulation (EC) No. 1272/2008 [CLP]

16.2 Abbreviations and acronyms

ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road

ATE = Acute Toxicity Estimates

CAS = Chemical Abstracts Service

CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]

CMR = Carcinogen, Mutagen or Reproductive toxicant

CO₂ = Carbon dioxide

DMEL = Derived Minimal Effect Level

DNEL = Derived No Effect Level

EC = European Commission

EC50 = Half maximal effective concentration

EN = European Standard (Norm)

EU = European Union

EUH statement = CLP-specific Hazard statement

EWC = European Waste Catalogue

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

H statement = GHS Hazard statement

IATA = International Air Transport Association ICAO-TI = International Civil Aviation Organization-Technical Instructions

IMDG = International Maritime Dangerous Goods

LC50 = Median lethal concentration

LD50 = Median lethal dose

LogPow = Logarithm of the octanol/water partition coefficient

MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)

NOEC/NOEL = No observed effect concentration/level

OECD = Organisation for Economic Co-operation and Development

PBT = Persistent, Bioaccumulative and Toxic

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PNEC = Predicted No Effect Concentration
REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation [Regulation (EC) No. 1907/2006]
RID = The Regulations concerning the International Carriage of Dangerous Goods by Rail
RMM = Risk Management Measure
RRN = REACH Registration Number
STOT-RE = Specific Target Organ Toxicity - Repeated Exposure
STOT-SE = Specific Target Organ Toxicity - Single Exposure
SVHC = Substances of Very High Concern
TLV/STEL = Threshold limit value/short-term exposure limit
TLV/TWA = Threshold limit value/time weighted average
UN = United Nations
VOC = Volatile Organic Compound
vPvB = Very Persistent and Very Bioaccumulative

16.3 Key literature references and sources for data

None

16.4 Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

No information available.

16.5 Relevant H- and EUH-phrases (Number and full text)

H272	May intensify fire; oxidiser.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H412	Harmful to aquatic life with long lasting effects.

16.6 Training advice

None

16.7 Additional information

Notice the directions for use on the label.

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.
