

Safety Data Sheet

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

Trade name : FD 366 sensitive wipes Disinfection of sensitive surfaces
Revision date : 11.10.2022
Print date : 13.10.2022
Version (Revision) : 4.0.0 (3.0.0)

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

1.1 Product identifier

FD 366 sensitive wipes Disinfection of sensitive surfaces
Unique Formula Identifier : ACP2-CJS7-HA0Y-PN59

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

Relevant identified uses

FD 366 sensitive wipes are suitable for the rapid disinfection of sensitive surfaces of medical devices.

Products Category [PC]

PC 0 - 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

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, 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

Warning

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Hazard statements

H319 Causes serious eye irritation.

Precautionary statements

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

The mixture does not contain any substances that have endocrine disrupting properties. The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description

FD 366 sensitive wipes contain alcohols, quaternary ammonium compounds and auxiliary agents in aqueous solution.

Hazardous ingredients

1-PROPANOL ; REACH No. : 01-2119486761-29 ; EC No. : 200-746-9; CAS No. : 71-23-8

Weight fraction : $\geq 15 - < 20$ %

Classification 1272/2008 [CLP] : Flam. Liq. 2 ; H225 Eye Dam. 1 ; H318 STOT SE 3 ; H336

DODECYLDIMETHYLBENZYLAMMONIUM CHLORIDE ; REACH No. : - ; EC No. : 287-089-1; CAS No. : 85409-22-9

Weight fraction : $\geq 0,025 - < 0,25$ %

Classification 1272/2008 [CLP] : Skin Corr. 1B ; H314 Eye Dam. 1 ; H318 Acute Tox. 4 ; H302 Aquatic Acute 1 ; H400 Aquatic Chronic 1 ; H410

Specific Conc. Limits : (M Chronic=1) • (M Acute=10)

Additional information

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information

When in doubt or if symptoms are observed, get medical advice.

Following inhalation

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

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.

Following ingestion

No special measures are necessary. Never give anything by mouth to an unconscious person or a person with cramps.

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

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Suitable extinguishing media

Carbon dioxide (CO₂) Extinguishing powder Water spray jet Water mist The product itself does not burn. Co-ordinate fire-fighting measures to the fire surroundings.

Unsuitable extinguishing media

Full water jet

5.2 Special hazards arising from the substance or mixture

None known.

Hazardous combustion products

None known.

5.3 Advice for firefighters

Adapt protective equipment to surrounding fire.

Special protective equipment for firefighters

Adapt protective equipment to surrounding fire.

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. Dispose of used cloths in the household waste - do not throw them down the toilet.

6.3 Methods and material for containment and cleaning up

For cleaning up

No special measures are necessary.

Other information

Dispose of used cloths in the household waste - do not throw them down the toilet.

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.

Protective measures

Measures to prevent fire

Usual measures for fire prevention. When using do not smoke.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep/Store only in original container. Keep container tightly closed. Keep containers in a well-ventilated place.

Hints on joint storage

Store the foodstuffs separately.

7.3 Specific end use(s)

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None

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values

1-PROPANOL ; CAS No. : 71-23-8

Limit value type (country of origin) : TLV/STEL (GB)
Limit value : 250 ppm / 625 mg/m³
Limit value type (country of origin) : TLV/TWA (GB)
Limit value : 200 ppm / 500 mg/m³

DNEL-/PNEC-values

There are no data available on the preparation itself.

DNEL/DMEL

1-PROPANOL ; CAS No. : 71-23-8

Limit value type : DNEL Consumer (systemic)
Exposure route : Inhalation
Exposure frequency : Short-term
Limit value : 1036 mg/m³
Limit value type : DNEL Consumer (systemic)
Exposure route : Dermal
Exposure frequency : Long-term
Limit value : 81 mg/kg
Limit value type : DNEL Consumer (systemic)
Exposure route : Inhalation
Exposure frequency : Long-term
Limit value : 80 mg/m³
Limit value type : DNEL Consumer (systemic)
Exposure route : Oral
Exposure frequency : Long-term
Limit value : 61 mg/kg
Limit value type : DNEL worker (systemic)
Exposure route : Inhalation
Exposure frequency : Short-term
Limit value : 1723 mg/m³
Limit value type : DNEL worker (systemic)
Exposure route : Dermal
Exposure frequency : Long-term
Limit value : 136 mg/kg
Limit value type : DNEL worker (systemic)
Exposure route : Inhalation
Exposure frequency : Long-term
Limit value : 268 mg/m³

PNEC

1-PROPANOL ; CAS No. : 71-23-8

Limit value type : PNEC (Aquatic, freshwater)
Limit value : 10 mg/l
Limit value type : PNEC (Aquatic, freshwater)
Limit value : 6,83 mg/l
Limit value type : PNEC (Aquatic, marine water)
Limit value : 1 mg/l
Limit value type : PNEC (Aquatic, marine water)
Limit value : 0,683 mg/l
Limit value type : PNEC (Industrial)

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Exposure route :	Soil
Limit value :	2,2 mg/kg
Limit value type :	PNEC (Sediment, freshwater)
Limit value :	22,8 mg/kg
Limit value type :	PNEC (Sediment, freshwater)
Limit value :	27,5 mg/kg
Limit value type :	PNEC (Sediment, marine water)
Limit value :	2,28 mg/kg
Limit value type :	PNEC (Sediment, marine water)
Limit value :	2,75 mg/kg
Limit value type :	PNEC (Soil)
Limit value :	1,49 mg/kg
Limit value type :	PNEC (Sewage treatment plant)
Exposure route :	Water (Including sewage plant)
Limit value :	96 mg/l

DODECYLDIMETHYLBENZYLAMMONIUM CHLORIDE ; CAS No. : 85409-22-9

Limit value type :	PNEC (Aquatic, freshwater)
Limit value :	0,00034 mg/l
Limit value type :	PNEC (Aquatic, marine water)
Limit value :	0,0342 ppm
Limit value type :	PNEC (Sediment, freshwater)
Limit value :	5,61 mg/kg
Limit value type :	PNEC (Sediment, marine water)
Limit value :	0,561 mg/kg
Limit value type :	PNEC (Sewage treatment plant)
Limit value :	0,273 mg/l

8.2 Exposure controls

Personal protection equipment

Eye/face protection

Eye glasses with side protection

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

Body protection: not required.

Respiratory protection

No special measures are necessary.

General information

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

Other protection measures

Provide adequate ventilation.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Soaking solution - wipes

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Appearance : wipes

Colour : white

Odour : Alcohol

Safety characteristics

Melting point/freezing point :	(1013 hPa)				not applicable
Initial boiling point and boiling range :	(1013 hPa)				not applicable
Decomposition temperature :	(1013 hPa)				not determined
Flash point :					not applicable
Auto-ignition temperature :					not applicable
Lower explosion limit :					not applicable
Upper explosion limit :					not applicable
Density :	(20 °C)	approx.	0,97	g/cm ³	
Solvent separation test :	(20 °C)	<	3	%	
Water solubility :	(20 °C)		100	Weight-%	
pH value :			6,5 - 7,5		
log P O/W :			not determined		
Flow time :	(20 °C)	<	20	s	DIN-cup 4 mm
Odour threshold :			not determined		
Maximum VOC content (EC) :			17	Weight-%	
Flammable solids :	Not fulfilling criteria for hazard class "Flammable Solids".				
Oxidising solids :	Not applicable.				
Explosive properties :	Not applicable.				
Corrosive to metals :	Not corrosive to metals.				

9.2 Other information

None

SECTION 10: Stability and reactivity

10.1 Reactivity

None, if handled according to order.

10.2 Chemical stability

Stable under recommended storage and handling conditions (see section 7).

10.3 Possibility of hazardous reactions

None, if handled according to order.

10.4 Conditions to avoid

No information available.

10.5 Incompatible materials

No information available.

10.6 Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Concentrate:

Acute toxicity

Based on available data, the classification criteria are not met.

Acute oral toxicity

Parameter :	LD50
Exposure route :	Oral
Species :	Rat

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Effective dose : > 2000 mg/kg
Method : OECD 423
Parameter : ATEmix calculated
Exposure route : Oral
Effective dose : not relevant
Parameter : ATE (DODECYLDIMETHYLBENZYLAMMONIUM CHLORIDE ; CAS No. : 85409-22-9)
Exposure route : Oral
Effective dose : 500 mg/kg

Acute dermal toxicity

Parameter : LD50
Exposure route : Dermal
Species : Rat
Effective dose : > 2000 mg/kg
Method : OECD 402
Parameter : ATEmix calculated
Exposure route : Dermal
Effective dose : not relevant

Acute inhalation toxicity

Parameter : ATEmix calculated
Exposure route : Inhalation (dust/mist)
Effective dose : not relevant
Parameter : LC50 (1-PROPANOL ; CAS No. : 71-23-8)
Exposure route : Inhalation
Species : Rat
Effective dose : > 33,8 mg/l
Exposure time : 4 h
Method : OECD 403

Corrosion

Skin corrosion/irritation

Based on available data, the classification criteria are not met. Patch testing: non-irritant.

Serious eye damage/eye irritation

Causes serious eye irritation. OECD 437

Respiratory or skin sensitisation

Based on available data, the classification criteria are not met.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity

Based on available data, the classification criteria are not met.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Reproductive toxicity

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

11.2 Information on other hazards

Endocrine disrupting properties

The mixture does not contain any substances that have endocrine disrupting properties.

Additional information

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

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as in-house investigations.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity

Based on available data, the classification criteria are not met.

Acute (short-term) fish toxicity

Parameter : LC50 (1-PROPANOL ; CAS No. : 71-23-8)
Species : Pimephales promelas (fathead minnow)
Evaluation parameter : Acute (short-term) fish toxicity
Effective dose : 4480 mg/l
Exposure time : 96 h
Parameter : LC50 (DODECYLDIMETHYLBENZYLAMMONIUM CHLORIDE ; CAS No. : 85409-22-9)
Species : Poecilia reticulata (Guppy)
Evaluation parameter : Acute (short-term) fish toxicity
Effective dose : 2 mg/l
Exposure time : 96 h
Parameter : LC50 (DODECYLDIMETHYLBENZYLAMMONIUM CHLORIDE ; CAS No. : 85409-22-9)
Species : Oncorhynchus mykiss (Rainbow trout)
Evaluation parameter : Acute (short-term) fish toxicity
Effective dose : 2 mg/l
Exposure time : 96 h
Parameter : LC50 (DODECYLDIMETHYLBENZYLAMMONIUM CHLORIDE ; CAS No. : 85409-22-9)
Species : Danio rerio (zebrafish)
Evaluation parameter : Acute (short-term) fish toxicity
Effective dose : 10 - 100 mg/l
Exposure time : 96 h
Method : OECD 203

Chronic (long-term) fish toxicity

Parameter : NOEC (DODECYLDIMETHYLBENZYLAMMONIUM CHLORIDE ; CAS No. : 85409-22-9)
Species : Pimephales promelas (fathead minnow)
Evaluation parameter : Chronic (long-term) fish toxicity
Effective dose : 0,032 mg/l
Exposure time : 816 h

Acute (short-term) toxicity to crustacea

Parameter : EC50 (1-PROPANOL ; CAS No. : 71-23-8)
Species : Daphnia magna (Big water flea)
Evaluation parameter : Acute (short-term) daphnia toxicity
Effective dose : 3644 mg/l
Exposure time : 48 h
Parameter : EC50 (DODECYLDIMETHYLBENZYLAMMONIUM CHLORIDE ; CAS No. : 85409-22-9)
Species : Daphnia magna (Big water flea)
Evaluation parameter : Acute (short-term) daphnia toxicity
Effective dose : 0,032 mg/l
Exposure time : 48 h
Method : OECD 202

Chronic (long-term) toxicity to aquatic invertebrate

Parameter : NOEC (1-PROPANOL ; CAS No. : 71-23-8)
Species : Daphnia magna (Big water flea)
Evaluation parameter : Chronic (long-term) daphnia toxicity
Effective dose : > 100 mg/l
Exposure time : 504 h
Method : OECD 211

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Parameter : NOEC (DODECYLDIMETHYLBENZYLAMMONIUM CHLORIDE ; CAS No. : 85409-22-9)
Species : Daphnia magna (Big water flea)
Evaluation parameter : Chronic (long-term) daphnia toxicity
Effective dose : 0,0042 mg/l
Exposure time : 504 h

Acute (short-term) toxicity to algae and cyanobacteria

Parameter : EC50 (1-PROPANOL ; CAS No. : 71-23-8)
Species : Scenedesmus subspicatus
Evaluation parameter : Inhibition of growth rate
Effective dose : 3100 mg/l
Exposure time : 168 h

Parameter : EC50 (DODECYLDIMETHYLBENZYLAMMONIUM CHLORIDE ; CAS No. : 85409-22-9)
Species : Pseudokirchneriella subcapitata
Evaluation parameter : Acute (short-term) algae toxicity
Effective dose : 0,02 mg/l
Exposure time : 72 h
Method : OECD 201

Parameter : EC50 (1-PROPANOL ; CAS No. : 71-23-8)
Species : Pseudokirchneriella subcapitata
Evaluation parameter : Acute (short-term) algae toxicity
Effective dose : 9170 mg/l
Exposure time : 48 h

Chronic (long-term) toxicity to aquatic algae and cyanobacteria

Parameter : NOEC (1-PROPANOL ; CAS No. : 71-23-8)
Species : Algae
Evaluation parameter : Chronic (long-term) algae toxicity
Effective dose : 1150 mg/l
Exposure time : 48 h

Toxicity to microorganisms

Parameter : EC50 (1-PROPANOL ; CAS No. : 71-23-8)
Species : Pseudomonas putida
Evaluation parameter : Bacteria toxicity
Effective dose : 2700 mg/l
Exposure time : 16 h

Parameter : EC50 (DODECYLDIMETHYLBENZYLAMMONIUM CHLORIDE ; CAS No. : 85409-22-9)
Evaluation parameter : Bacteria toxicity
Effective dose : 7,75 mg/l
Exposure time : 3 h
Method : OECD 209

Parameter : EC50 (DODECYLDIMETHYLBENZYLAMMONIUM CHLORIDE ; CAS No. : 85409-22-9)
Evaluation parameter : Bacteria toxicity
Effective dose : 7,03 mg/l
Exposure time : 21 h
Method : OECD 209

Parameter : EC50 (1-PROPANOL ; CAS No. : 71-23-8)
Evaluation parameter : Bacteria toxicity
Effective dose : > 1000 mg/l
Exposure time : 3 h
Method : OECD 209

12.2 Persistence and degradability

Abiotic degradation

No data available.

Biodegradation

not applicable

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12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

Distribution

Wipes: 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 REACH, annex XIII.

12.6 Endocrine disrupting properties

The mixture does not contain any substances that have endocrine disrupting properties.

12.7 Other adverse effects

No information available.

12.8 Additional ecotoxicological information

Do not allow to enter into surface water or drains. Dispose of used cloths in the household waste - do not throw them down the toilet.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Directive 2008/98/EC (Waste Framework Directive)

After intended use

Disposal operations

Dispose according to legislation. Dispose of used cloths in the household waste - do not throw them down the toilet. Consult the appropriate local waste disposal expert about waste disposal.

Recovery operations

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

Waste codes/waste designations according to EWC/AVV

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

SECTION 14: Transport information

14.1 UN number

No dangerous good in sense of these transport regulations.

14.2 UN proper shipping name

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 Maritime transport in bulk according to IMO instruments

not applicable

SECTION 15: Regulatory information

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

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mixture

EU legislation

Authorisations and/or restrictions on use

Restrictions on use

Regulation (EC) No. 1907/2006 (REACH), Annex XVII (restrictions)

Use restriction according to REACH annex XVII, no. : 3, 40, 75

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. Classification of the substance or mixture · 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
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

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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]

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

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

H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H336	May cause drowsiness or dizziness.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

16.6 Training advice

None

16.7 Additional information

Follow the instructions 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.
