

Safety Data Sheet

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

Trade name : FD 366 sensitive Disinfection of sensitive surfaces
Revision : 18.05.2022
Print date : 18.05.2022

Version (Revision) : 3.0.2 (3.0.1)

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

1.1 Product identifier

FD 366 sensitive Disinfection of sensitive surfaces

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

Relevant identified uses

FD 366 sensitive is an aldehyde-free working solution for the quick-acting, alcoholic spray and wipe disinfection and cleaning of the sensitive surfaces of medical devices.

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

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Postal code/city : 70806 Kornwestheim

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DÜRR DENTAL SE, PO Box 2067, Woonona East New South Wales 2517, Australia, Frank Schröder, Tel.: 1300 52 53 51

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Ivoclar Vivadent Ltd, 12 Omega Street, Rosedale, Auckland 0632, New Zealand. Customer Services Phone: 0508 486 252
Telephone: +64 9 914 9999 Fax: +64 9 914 9990 Email: Customercare.nz@ivoclar.com

1.4 Emergency telephone number

National Poisons Centre: 0800 764 766 / 24 hours a day, 7 days a week New Zealand wide.

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 2A ; Causes serious eye irritation.

Flam. Liq. 3 ; H226 - Flammable liquids : Category 3 ; Flammable liquid and vapour.

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



Flame (GHS02) · Exclamation mark (GHS07)

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Signal word

Warning

Hazard statements

H226 Flammable liquid and vapour.
H319 Causes serious eye irritation.

Precautionary statements

P211 Do not spray on an open flame or other ignition source.
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

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

Hazardous ingredients

1-PROPANOL ; REACH registration 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 registration No. : - ; EC No. : 287-089-1; CAS No. : 85409-22-9

Weight fraction : $< 0,5$ %

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

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

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

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 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

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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Carbon dioxide (CO₂) Extinguishing powder Water spray Water mist

Unsuitable extinguishing media

Full water jet

5.2 Special hazards arising from the substance or mixture

None known.

Hazardous combustion products

Vapours can form explosive mixtures with air.

5.3 Advice for firefighters

Cool endangered containers with water in case of fire.

Special protective equipment for firefighters

In case of fire: Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protection equipment. Remove all sources of ignition. When using do not smoke. 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

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Collect in closed and suitable containers for disposal.

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. Keep away from sources of ignition. - No smoking. Provide adequate ventilation. Do not breathe vapour/aerosol.

Protective measures

Measures to prevent fire

Usual measures for fire prevention. Keep away from sources of ignition. - No smoking.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

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Keep/Store only in original container. Keep container tightly closed. Keep in a cool, well-ventilated place. Do not store in temperatures below 5 °C.

Hints on joint storage

Do not store together with oxidizing, self-igniting substances and highly flammable solid substances. 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) (1-PROPANOL ; CAS No. : 71-23-8)
Exposure route :	Inhalation
Exposure frequency :	Short-term (acute)
Limit value :	1036 mg/m ³
Limit value type :	DNEL Consumer (systemic) (1-PROPANOL ; CAS No. : 71-23-8)
Exposure route :	Dermal
Exposure frequency :	Long-term (repeated)
Limit value :	81 mg/kg
Limit value type :	DNEL Consumer (systemic) (1-PROPANOL ; CAS No. : 71-23-8)
Exposure route :	Inhalation
Exposure frequency :	Long-term (repeated)
Limit value :	80 mg/m ³
Limit value type :	DNEL Consumer (systemic) (1-PROPANOL ; CAS No. : 71-23-8)
Exposure route :	Oral
Exposure frequency :	Long-term (repeated)
Limit value :	61 mg/kg
Limit value type :	DNEL worker (systemic) (1-PROPANOL ; CAS No. : 71-23-8)
Exposure route :	Inhalation
Exposure frequency :	Short-term (acute)
Limit value :	1723 mg/m ³
Limit value type :	DNEL worker (systemic) (1-PROPANOL ; CAS No. : 71-23-8)
Exposure route :	Dermal
Exposure frequency :	Long-term (repeated)
Limit value :	136 mg/kg
Limit value type :	DNEL worker (systemic) (1-PROPANOL ; CAS No. : 71-23-8)
Exposure route :	Inhalation
Exposure frequency :	Long-term (repeated)
Limit value :	268 mg/m ³

PNEC

Limit value type :	PNEC aquatic, freshwater (1-PROPANOL ; CAS No. : 71-23-8)
Limit value :	10 mg/l
Limit value type :	PNEC aquatic, marine water (1-PROPANOL ; CAS No. : 71-23-8)
Limit value :	1 mg/l
Limit value type :	PNEC (Industrial) (1-PROPANOL ; CAS No. : 71-23-8)
Exposure route :	Soil
Limit value :	2,2 mg/kg
Limit value type :	PNEC sediment, freshwater (1-PROPANOL ; CAS No. : 71-23-8)
Limit value :	22,8 mg/kg
Limit value type :	PNEC sediment, marine water (1-PROPANOL ; CAS No. : 71-23-8)
Limit value :	2,28 mg/kg

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Limit value type : PNEC sewage treatment plant (STP) (1-PROPANOL ; CAS No. : 71-23-8)
Exposure route : Water (Including sewage plant)
Limit value : 96 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

Body protection: not required.

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. Remove contaminated, saturated clothing. 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 : liquid

Colour : colourless

Odour : Alcohol

Safety relevant basis data

Melting point/melting range :	(1013 hPa)	No data available	
Initial boiling point and boiling range :	(1013 hPa)	No data available	
Decomposition temperature :	(1013 hPa)	No data available	
Flash point :		33 °C	
Ignition temperature :		371 °C	
Lower explosion limit :		2,1 Vol-%	
Upper explosion limit :		19,2 Vol-%	
Vapour pressure :	(50 °C)	No data available	
Density :	(20 °C)	0,95 - 0,99 g/cm ³	
Solvent separation test :	(20 °C)	< 3 %	
Water solubility :	(20 °C)	100 Wt %	
pH value :		6,5 - 7,5	
log P O/W :		No data available	
Flow time :	(20 °C)	< 20 s	DIN-cup 4 mm
Odour threshold :		No data available	
Maximum VOC content (EC) :		17 Wt %	
Oxidising liquids :	Not applicable.		
Explosive properties :	Not applicable.		

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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

Vapours can form explosive mixtures with air.

10.4 Conditions to avoid

No information available.

10.5 Incompatible materials

Oxidising agent.

10.6 Hazardous decomposition products

None known.

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 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

Practical experience/human evidence

There is no inhalation risk under normal application conditions.

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 :	Inhalative (vapour)
Effective dose :	not relevant
Parameter :	LC50 (1-PROPANOL ; CAS No. : 71-23-8)
Exposure route :	Inhalation

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Species : Rat
Effective dose : > 33,8 mg/l
Exposure time : 4 h
Method : OECD 403

Irritant and corrosive effects

Causes serious eye irritation.

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

There are no data available on the preparation itself.

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 : Pimephales promelas (fathead minnow)
Evaluation parameter : Acute (short-term) fish toxicity
Effective dose : 0,28 mg/l
Exposure time : 96 h

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) daphnia toxicity

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 : 0,016 mg/l
Exposure time : 48 h

Chronic (long-term) daphnia toxicity

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

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Method : OECD 211
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) algae toxicity

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 : ErC50 (DODECYLDIMETHYLBENZYLAMMONIUM CHLORIDE ; CAS No. : 85409-22-9)
Species : Pseudokirchneriella subcapitata
Effective dose : 0,049 mg/l
Exposure time : 72 h

Chronic (long-term) algae toxicity

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

Bacteria toxicity

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
Exposure time : 3 h
Method : OECD 209

12.2 Persistence and degradability

Abiotic degradation

No data available.

Biodegradation

Readily biodegradable (according to OECD criteria).

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

Prevent from flowing into surface water/ground water.

SECTION 13: Disposal considerations

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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

UN 1274

14.2 UN proper shipping name

Land transport (ADR/RID)

N-PROPANOL

Sea transport (IMDG)

N-PROPANOL

Air transport (ICAO-TI / IATA-DGR)

N-PROPANOL

14.3 Transport hazard class(es)

Land transport (ADR/RID)

Class(es) : 3
Classification code : F1
Hazard identification number (Kemler No.) : 30
Tunnel restriction code : D/E
Special provisions : LQ 5 I · LQ 7 · E 1
Hazard label(s) : 3

Sea transport (IMDG)

Class(es) : 3
EmS-No. : F-E / S-D
Special provisions : LQ 5 I · E 1
Hazard label(s) : 3

Air transport (ICAO-TI / IATA-DGR)

Class(es) : 3
Special provisions : E 1
Hazard label(s) : 3

14.4 Packing group

III

14.5 Environmental hazards

Land transport (ADR/RID) : No

Sea transport (IMDG) : No

Air transport (ICAO-TI / IATA-DGR) : No

14.6 Special precautions for user

None

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

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not applicable

SECTION 15: Regulatory information

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

Approval Code: HSR002556
Group Standard: Dental Products Flammable Group Standard 2020

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. Label elements

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

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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) 1272/2008 [CLP]

No information available.

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.

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.
