

Safety Data Sheet

according to GHS

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

Version : 1.0.1 (1.0.0)

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

1.1 Product identifier

FD 366 sensitive top wipes Disinfection of sensitive surfaces

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

Relevant identified uses

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

Product Categories [PC]

PC0 - 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 (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 Australia:

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

Distributor:

Ivoclar Vivadent Pty Ltd, 1-5 Overseas Drive Noble Park North, VIC 3174, Melbourne, Australia, Phone: 1300 486 252

E-mail: Customercare.au@ivoclar.com

1.4 Emergency telephone number

Poisons Information Centre: Dial 13 11 26

24 hours a day, 7 days a week Australia wide

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to GHS

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 GHS as well as in-house investigations.

2.2 Label elements

Labelling according to GHS

Hazard pictograms



Exclamation mark (GHS07)

Signal word

Warning

Hazard statements

H319

Causes serious eye irritation.

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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

None

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description

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

Hazardous ingredients

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 [GHS] : Flam. Liq. 2 ; H225 Eye Dam. 1 ; H318 STOT SE 3 ; H336

DODECYLDIMETHYLBENZYLAMMONIUM CHLORIDE ; REACH No. : 012119970550-39 ; EC No. : 287-089-1; CAS No. : 85409-22-9 (M Acute=10) (M Chronic=1)

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

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

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

No special measures are necessary.

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

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

Suitable extinguishing media

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Carbon dioxide (CO₂) Extinguishing powder Water spray 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

No special environmental measures are necessary.

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.

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. Do not store in temperatures below 5 °C.

Hints on joint storage

Store the foodstuffs separately.

7.3 Specific end use(s)

None

SECTION 8: Exposure controls/personal protection

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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
Limit value type :	PNEC (Sewage treatment plant) (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

Use tightly fitting safety glasses as per Australian Standard AS 1336 and AS/NZS 1337. Safety glasses with side shields

Skin protection

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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. Wear impervious rubber gloves (AS2161).

Body protection

Body protection: not required.

Respiratory protection

No special measures are necessary.

General health and safety measures

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.

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 : wipes

Colour : white

Odour : Alcohol

Safety relevant basis data

Melting point/melting range :	(1013 hPa)	not applicable
Initial boiling point and boiling range :	(1013 hPa)	not applicable
Decomposition temperature :	(1013 hPa)	not applicable
Flash point :		not applicable
Ignition temperature :		not applicable
Lower explosion limit :		not applicable
Upper explosion limit :		not applicable
Density :	(20 °C)	none
Solvent separation test :	(20 °C)	not applicable
Water solubility :	(20 °C)	not relevant
pH value :		not applicable
log P O/W :		not applicable
Flow time :	(20 °C)	not applicable
Odour threshold :		not determined
Maximum VOC content (EC) :		17 Wt %
Flammable solids :	Not fulfilling criteria for hazard class "Flammable Solids".	
Oxidising liquids :	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

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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 toxicological effects

Concentrate:

Acute toxicity

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

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 :	Inhalation (vapour)
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: Not an irritant.

Serious eye damage/eye irritation

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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.

11.5 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

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 :	Pimephales promelas (fathead minnow)
Evaluation parameter :	Acute (short-term) fish toxicity
Effective dose :	0,28 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 :	0,85 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

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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) toxicity to crustacea

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

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 aquatic 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) 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

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

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Method : OECD 209

12.2 Persistence and degradability

Abiotic degradation

No data available.

Biodegradation

Concentrate: Readily biodegradable (according to OECD criteria).

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 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

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. Contact a specialist disposal company or the local waste regulator for advice. This should be done in accordance with 'The Hazardous Waste Act'. Can be eliminated with domestic garbage on condition it complies with local regulations.

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

not applicable

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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

None

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
vPvB = Very Persistent and Very Bioaccumulative

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16.3 Key literature references and sources for data

Standard EN420:2003 General requirements for protective gloves: disposable gloves, e.g. nitrile rubber, material thickness 0.1 mm (Australian Standard 2161).

Long-term exposure (Level 6: < 480 min): protective gloves, e.g. nitrile rubber, material thickness 0.7 mm (Australian Standard 2161).

Personal eye protection - Eye and face protectors for occupational applications: safety glasses (Australian Standard AS 1336 and AS/NZS 1337.1:2010).

16.4 Classification for mixtures and used evaluation method according to GHS

The classification was carried out according to the calculation method of GHS 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

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.
