

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 18.05.2021

Version number 3

Revision: 18.05.2021

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

- **1.1 Product identifier**
- **Trade name: FotoDent IBT 385 nm**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture**
Material for the manufacturing of dental indirect bonding trays
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Dreve Dentamid GmbH
Max-Planck-Straße 31
59423 Unna / Germany
Tel.: ++49 2303 /8807-0
Fax.: ++49 2303 / 8807-55
- **Further information obtainable from:**
Department Research & Development
Fax: ++49 2303 / 8807-562
Email: sicherheitsdatenblatt@dreve.de
- **1.4 Emergency telephone number:**
Tel.: ++ 49 211 / 797-3350
Plant Fire Department Henkel

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS08 health hazard

Repr. 2 H361d Suspected of damaging the unborn child.



GHS09 environment

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07



GHS08



GHS09

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Trade name: FotoDent IBT 385 nm

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- **Signal word** Warning
- **Hazard-determining components of labelling:**
2-phenoxyethyl methacrylate
Aliphatic difunctional Urethane Acrylate
(5-ethyl-1,3-dioxan-5-yl)methyl acrylate
Urethantrimethacrylate, aliphatic
- **Hazard statements**
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H361d Suspected of damaging the unborn child.
H411 Toxic to aquatic life with long lasting effects.
- **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P273 Avoid release to the environment.
P280 Wear protective gloves / eye protection / face protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Additional information:**
Contains isocyanates. May produce an allergic reaction.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

	Aliphatic difunctional Urethane Acrylate ⚠ Skin Sens. 1, H317	25-50%
CAS: 66492-51-1 EINECS: 266-380-7	(5-ethyl-1,3-dioxan-5-yl)methyl acrylate ⚠ Aquatic Chronic 2, H411; ⚠ Skin Irrit. 2, H315; Skin Sens. 1, H317	25-50%
CAS: 10595-06-9 EINECS: 234-201-1	2-phenoxyethyl methacrylate ⚠ Repr. 2, H361d; ⚠ Aquatic Chronic 2, H411; ⚠ Skin Sens. 1, H317	25-50%
CAS: 29964-84-9 EINECS: 249-978-2	isodecyl methacrylate ⚠ Aquatic Acute 1, H400; ⚠ Aquatic Chronic 1, H410; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	2.5-10%
	Urethantrimethacrylate, aliphatic ⚠ Skin Sens. 1, H317; ⚠ Aquatic Chronic 4, H413	2.5-10%
CAS: 75980-60-8 EINECS: 278-355-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphin oxide ⚠ Repr. 2, H361f	≤2.5%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

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SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:**
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.
- **After eye contact:**
Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**
Do not induce vomiting.
Call a doctor immediately.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire extinguishing methods suitable to surrounding conditions.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **5.2 Special hazards arising from the substance or mixture**
No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Avoid contact with skin and eyes.
- **6.2 Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

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SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**

Avoid contact with skin and eyes.
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Prevent formation of aerosols.

- **Information about fire - and explosion protection:** Keep respiratory protective device available.

- **7.2 Conditions for safe storage, including any incompatibilities**

- **Storage:**

- **Requirements to be met by storerooms and receptacles:** Protect from heat and direct sunlight.

- **Information about storage in one common storage facility:** Not required.

- **Further information about storage conditions:** Keep container tightly sealed.

- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.

- **8.1 Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- **Additional information:** The lists valid during the making were used as basis.

- **8.2 Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Store protective clothing separately.
Avoid contact with the eyes and skin.

- **Respiratory protection:**

Do not inhale fumes.
Use suitable respiratory protective device in case of insufficient ventilation.

- **Protection of hands:**



Protective gloves

Protective gloves should be changed regularly, especially after intensive contact with the product. For every workplace a suitable type of protective gloves must be selected.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

- **Material of gloves**

Nitrile rubber, NBR (0,4 mm)

As there are many different conditions in every day work these indications can only serve as an aid to orientation for the selection of suitable gloves for the handling of chemical products. By no means they can replace qualifying examinations by the end-user.

These recommendations only apply to the product mentioned in the safety data sheet. When mixing with other substances or under conditions deviant from norm EN 374 a manufacturer of CE-approved gloves should be referred to.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of

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several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

The determined penetration times according to EN 16523-1:2015 are not performed under practical conditions. Therefore a maximum wearing time, which corresponds to 50% of the penetration time, is recommended.

- **Eye protection:** Goggles recommended during refilling
- **Body protection:** Protective work clothing

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form: Fluid

Colour: Clear transparent

- **Odour:** Characteristic

- **Odour threshold:** Not determined.

- **pH-value:** Not determined.

- **Change in condition**

Melting point/freezing point: Undetermined.

Initial boiling point and boiling range: 149 °C

- **Flash point:** 100 °C

- **Flammability (solid, gas):** Not applicable.

- **Ignition temperature:** 295 °C

- **Decomposition temperature:** Not determined.

- **Auto-ignition temperature:** Product is not selfigniting.

- **Explosive properties:** Product does not present an explosion hazard.

- **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

- **Oxidising properties** Not determined
Not applicable.

- **Vapour pressure:** Not determined.

- **Density at 20 °C:** 1.07 g/cm³

- **Relative density** Not determined.

- **Vapour density** Not determined.

- **Evaporation rate** Not determined.

- **Solubility in / Miscibility with water:**

Not miscible or difficult to mix.

- **Partition coefficient: n-octanol/water:** Not determined.

- **Viscosity:**

Dynamic: Not determined.

Kinematic: Not determined.

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- **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No dangerous reactions if used according to specifications.
- **10.2 Chemical stability** Stable if used according to specifications.
- **Thermal decomposition / conditions to be avoided:**
Protect from heat and direct sunlight.
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

- **LD/LC50 values relevant for classification:**

10595-06-9 2-phenoxyethyl methacrylate

Oral	LD50	5,000 mg/kg (rat)
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29964-84-9 isodecyl methacrylate

Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>3,000 mg/kg (rabbit)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity**
Suspected of damaging the unborn child.
- **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.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Toxic for fish

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- **Additional ecological information:**
- **General notes:**
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
Also poisonous for fish and plankton in water bodies.
Toxic for aquatic organisms
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
Disposal must be made according to official regulations.

- **European waste catalogue**

HP4	Irritant - skin irritation and eye damage
HP10	Toxic for reproduction
HP13	Sensitising
HP14	Ecotoxic

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|---|--|
| <ul style="list-style-type: none"> · 14.1 UN-Number · ADR, IMDG, IATA | UN3082 |
| <ul style="list-style-type: none"> · 14.2 UN proper shipping name · ADR · IMDG · IATA | 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. ((5-ethyl-1,3-dioxan-5-yl)methyl acrylate, 2-phenoxyethyl methacrylate)

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. ((5-ethyl-1,3-dioxan-5-yl)methyl acrylate, 2-phenoxyethyl methacrylate), MARINE POLLUTANT

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. ((5-ethyl-1,3-dioxan-5-yl)methyl acrylate, 2-phenoxyethyl methacrylate) |

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· **14.3 Transport hazard class(es)**

· ADR, IMDG, IATA



· **Class**

9 Miscellaneous dangerous substances and articles.

· **Label**

9

· **14.4 Packing group**

· ADR, IMDG, IATA

III

· **14.5 Environmental hazards:**

Product contains environmentally hazardous substances: (5-ethyl-1,3-dioxan-5-yl)methyl acrylate, 2-phenoxyethyl methacrylate

· **Marine pollutant:**

Yes

· **Special marking (ADR):**

Symbol (fish and tree)

· **Special marking (IATA):**

Symbol (fish and tree)

Symbol (fish and tree)

· **14.6 Special precautions for user**

Warning: Miscellaneous dangerous substances and articles.

· **Danger code (Kemler):**

90

· **EMS Number:**

F-A,S-F

· **Stowage Category**

A

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

Not applicable.

· **Transport/Additional information:**

According to special provision no 375 (ADR chapter 3.3), according to special provision no 969 (IMDG chapter 3.3 in conjunction with IMDG chapter 2.10.2.7) and according to special provision no A197 (IATA chapter 4.4) single - respectively inner packagings with a net quantity < 5 l / 5 kg aren't liable to the regulations, meaning those don't need to be sent as hazardous goods. Labelling with pictogram GHS09 is not necessary.

· **ADR**

· **Limited quantities (LQ)**

5L

· **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 1000

ml

· **Transport category**

3

· **IMDG**

· **Limited quantities (LQ)**

5L

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<ul style="list-style-type: none"> · Excepted quantities (EQ) 	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
<ul style="list-style-type: none"> · UN "Model Regulation": 	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. ((5-ETHYL-1,3-DIOXAN-5-YL)METHYL ACRYLATE, 2-PHENOXYETHYL METHACRYLATE), 9, III

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Seveso category** E2 Hazardous to the Aquatic Environment
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**
 - H315 Causes skin irritation.
 - H317 May cause an allergic skin reaction.
 - H319 Causes serious eye irritation.
 - H335 May cause respiratory irritation.
 - H361d Suspected of damaging the unborn child.
 - H361f Suspected of damaging fertility.
 - H400 Very toxic to aquatic life.
 - H410 Very toxic to aquatic life with long lasting effects.
 - H411 Toxic to aquatic life with long lasting effects.
 - H413 May cause long lasting harmful effects to aquatic life.
- **Department issuing SDS:** Department Research & Development
- **Contact:** Dr. Thomas Veit, Lothar Sutor, Susanne Weber
- **Abbreviations and acronyms:**
 - ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
 - IMDG: International Maritime Code for Dangerous Goods
 - IATA: International Air Transport Association
 - GHS: Globally Harmonised System of Classification and Labelling of Chemicals
 - EINECS: European Inventory of Existing Commercial Chemical Substances
 - ELINCS: European List of Notified Chemical Substances
 - CAS: Chemical Abstracts Service (division of the American Chemical Society)
 - LC50: Lethal concentration, 50 percent
 - LD50: Lethal dose, 50 percent
 - PBT: Persistent, Bioaccumulative and Toxic
 - vPvB: very Persistent and very Bioaccumulative
 - Skin Irrit. 2: Skin corrosion/irritation – Category 2
 - Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
 - Skin Sens. 1: Skin sensitisation – Category 1

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Repr. 2: Reproductive toxicity – Category 2

Repr. 2: Reproductive toxicity – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

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