

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

Printing date 12.07.2017

Version number 2

Revision: 12.07.2017

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

- **1.1 Product identifier**
- **Trade name: FotoDent Gingiva 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 based on methacrylate resin for DLP-systems with UV LED 385 nm for the manufacturing of gingiva masks
- **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**



GHS09 environment

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



GHS07

Skin Irrit. 2	H315 Causes skin irritation.
Eye Irrit. 2	H319 Causes serious eye 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 GHS09

- **Signal word** Warning
- **Hazard-determining components of labelling:**
Urethane acrylate in HPMA

(Contd. on page 2)



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

Printing date 12.07.2017

Version number 2

Revision: 12.07.2017

Trade name: FotoDent Gingiva 385 nm

(Contd. of page 1)

phenyl bis(2,4,6-trimethylbenzoyl)-phosphineoxide
Pigments

- **Hazard statements**

H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
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.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **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:**

	Urethane acrylate in HPMA ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10-25%
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%
CAS: 162881-26-7 ELINCS: 423-340-5	phenyl bis(2,4,6-trimethylbenzoyl)-phosphineoxide ⚠ Skin Sens. 1, H317; Aquatic Chronic 4, H413	≤ 2.5%
	Pigments ⚠ Eye Irrit. 2, H319; Skin Sens. 1, H317	≤ 2.5%

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

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.

(Contd. on page 3)



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

Printing date 12.07.2017

Version number 2

Revision: 12.07.2017

Trade name: FotoDent Gingiva 385 nm

(Contd. of page 2)

- **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.
- **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.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Avoid contact with skin and eyes.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** No special measures required.
- **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.

(Contd. on page 4)



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

Printing date 12.07.2017

Version number 2

Revision: 12.07.2017

Trade name: FotoDent Gingiva 385 nm

(Contd. of page 3)

- **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.

Avoid contact with the eyes and skin.

- **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

- **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**

Butyl rubber, BR

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 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 374 part III are not performed under practical conditions. Therefore a maximum wearing time, which corresponds to 50% of the penetration time, is recommended.

- **Eye protection:**



Tightly sealed goggles

- **Body protection:** Protective work clothing

GB

(Contd. on page 5)



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

Printing date 12.07.2017

Version number 2

Revision: 12.07.2017

Trade name: FotoDent Gingiva 385 nm

(Contd. of page 4)

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties	
· General Information	
· Appearance:	
Form:	Fluid
Colour:	Pink-opaque
· Odour:	Characteristic
· Odour threshold:	Not determined.
· pH-value:	Not determined.
· Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	263 °C
· Flash point:	70 °C
· Flammability (solid, gas):	Not applicable.
· Ignition temperature:	260 °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
· Vapour pressure:	Not determined.
· Density at 20 °C:	1.02 g/cm ³
· 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.
· Solvent content:	
Organic solvents:	0.0 %
· 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.

(Contd. on page 6)



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

Printing date 12.07.2017

Version number 2

Revision: 12.07.2017

Trade name: FotoDent Gingiva 385 nm

(Contd. of page 5)

- **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:**

29964-84-9 isodecyl methacrylate

Oral	LD50	> 5000 mg/kg (rat)
Dermal	LD50	> 3000 mg/kg (rabbit)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **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** 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.

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
- **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.

GB

(Contd. on page 7)



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

Printing date 12.07.2017

Version number 2

Revision: 12.07.2017

Trade name: FotoDent Gingiva 385 nm

(Contd. of page 6)

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**

HP 4	Irritant - skin irritation and eye damage
HP 13	Sensitising
HP 14	Ecotoxic

- **Uncleaned packaging:**

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

SECTION 14: Transport information

- **14.1 UN-Number**

- **ADR, ADN, IMDG, IATA** Void

- **14.2 UN proper shipping name**

- **ADR, ADN, IMDG, IATA** Void

- **14.3 Transport hazard class(es)**

- **ADR, ADN, IMDG, IATA**

- **Class** Void

- **14.4 Packing group**

- **ADR, IMDG, IATA** Void

- **14.5 Environmental hazards:**

- **Marine pollutant:** Yes

- **14.6 Special precautions for user** Not applicable.

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

Not applicable.

- **UN "Model Regulation":**

Void

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.

GB

(Contd. on page 8)



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

Printing date 12.07.2017

Version number 2

Revision: 12.07.2017

Trade name: FotoDent Gingiva 385 nm

(Contd. of page 7)

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.

H400 Very toxic to aquatic life.

H410 Very 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

- **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

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

- *** Data compared to the previous version altered.**

GB