

Safety Data Sheet

according to Regulation (EC) No 1907/2006

freeprint ortho® UV

Revision date: 24.07.2018

Product code: 839

Page 1 of 9

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

1.1. Product identifier

freeprint ortho® UV

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

Use of the substance/mixture

Light curing one component material for the fabrication of dental splints and guides.

1.3. Details of the supplier of the safety data sheet

Manufacturer

| | | |
|-------------------------|--|---------------------------|
| Company name: | DETAX GmbH & Co. KG | |
| Street: | Carl-Zeiss-Strasse | |
| Place: | D-76275 Ettlingen | |
| Telephone: | +49 7243/510-0 | Telefax: +49 7243/510-100 |
| e-mail: | post@detax.de | |
| Internet: | www.detax.de | |
| Responsible Department: | Emergency number: | |
| | +49 7243/510-0 | |
| | This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 a.m. - 4.00 p.m.) | |

Importer / Distributer

| | | |
|---------------|--|-------------------------------|
| Company name: | Ivoclar Vivadent Pty Ltd | |
| Place: | 1-5 Overseas Drive Noble Park North VIC 3174 | |
| Telephone: | +61 3 9795 9599 | Telefax: Fax: +61 3 9795 9645 |
| e-mail: | info@ivoclarvivadent.com | |

1.4. Emergency telephone number:

13 11 26
Poisons Hotline (24 hours / 7 days)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:

Skin corrosion/irritation: Skin Irrit. 2
 Serious eye damage/eye irritation: Eye Irrit. 2
 Respiratory or skin sensitisation: Skin Sens. 1A
 Specific target organ toxicity - single exposure: STOT SE 3

Hazard Statements:

Causes skin irritation.
 Causes serious eye irritation.
 May cause an allergic skin reaction.
 May cause respiratory irritation.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

isopropylidenediphenol peg-2 dimethacrylate
 Urethane Dimethacrylate
 Hydroxy propyl methacrylate
 tetrahydrofurfuryl methacrylate THFMA purified grade
 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
 2-hydroxyethyl methacrylate

Signal word: Warning

Pictograms:



according to Regulation (EC) No 1907/2006

freeprint ortho® UV

Revision date: 24.07.2018

Product code: 839

Page 2 of 9

Hazard statements

| | |
|------|--------------------------------------|
| H315 | Causes skin irritation. |
| H317 | May cause an allergic skin reaction. |
| H319 | Causes serious eye irritation. |
| H335 | May cause respiratory irritation. |

Precautionary statements

| | |
|-----------|---|
| P261 | Avoid breathing dust/fume/gas/mist/vapours/spray. |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection. |
| P302+P352 | IF ON SKIN: Wash with plenty of water. |
| P333+P313 | If skin irritation or rash occurs: Get medical advice/attention. |
| P362+P364 | Take off contaminated clothing and wash it before reuse. |
| P501 | Dispose of contents/ container in accordance with local and national regulations. |

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Mixture of acrylic/ methacrylic resins with auxilliary matters.

Hazardous components

| CAS No | Chemical name | | | Quantity |
|------------|--|--------------|------------------|-------------|
| | EC No | Index No | REACH No | |
| | Classification according to Regulation (EC) No. 1272/2008 [CLP] | | | |
| 41637-38-1 | isopropylidenediphenol peg-2 dimethacrylate | | | 25 - 50 % |
| | | | | |
| | Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1A, STOT SE 3; H315 H319 H317 H335 | | | |
| 72869-86-4 | Urethane Dimethacrylate | | | 10 - 25 % |
| | | | | |
| | Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335 | | | |
| 72829-09-5 | 1,12-Dodecanediol Dimethacrylate | | | 5 - 25 % |
| | | | | |
| | Skin Irrit. 2, Eye Irrit. 2; H315 H319 | | | |
| 27813-02-1 | Hydroxy propyl methacrylate | | | < 5 % |
| | 248-666-3 | | 01-2119490226-37 | |
| | Eye Irrit. 2, Skin Sens. 1; H319 H317 | | | |
| 2455-24-5 | tetrahydrofurfuryl methacrylate THFMA purified grade | | | 1 - 10 % |
| | | | | |
| | Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335 | | | |
| 75980-60-8 | diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide | | | 0,1 - < 5 % |
| | 278-355-8 | 015-203-00-X | | |
| | Repr. 2, Skin Sens. 1B, Aquatic Chronic 2; H361f H317 H411 | | | |
| 868-77-9 | 2-hydroxyethyl methacrylate | | | < 1 % |
| | 212-782-2 | 607-124-00-X | | |
| | Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1; H315 H319 H317 | | | |

Full text of H and EUH statements: see section 16.

according to Regulation (EC) No 1907/2006

freeprint ortho® UV

Revision date: 24.07.2018

Product code: 839

Page 3 of 9

SECTION 4: First aid measures**4.1. Description of first aid measures****After inhalation**

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

After contact with skin

After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

After contact with eyes

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

After ingestion

Rinse mouth immediately and drink plenty of water.

Seek immediately medical advice. Do not induce vomiting. In case of spontaneous vomiting take care of an unhindered flow out of the vomit (danger of suffocation).

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately.

Do not allow entering drains or surface water.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

according to Regulation (EC) No 1907/2006

freeprint ortho® UV

Revision date: 24.07.2018

Product code: 839

Page 4 of 9

Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep container tightly closed.

Advice on storage compatibility

Keep away from spontaneous flammable or combustible substances.

Further information on storage conditions

Keep only in the original container in a dry and well-ventilated place, away from foodstuffs. Keep away from all kind of lighth. An inert gas blanket should not be applied, because the stability of the product depends on the presence of oxygen (air).

7.3. Specific end use(s)

Lighth curing material for fabrication of dental splints and guides.
For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****8.2. Exposure controls****Appropriate engineering controls**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Protective and hygiene measures

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme.
Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

Eye/face protection

Suitable eye protection: goggles.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Suitable are gloves of the following material: Butyl caoutchouc (butyl rubber)

Skin protection

Wear suitable protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

| | |
|-----------------|---------------------|
| Physical state: | liquid: |
| Colour: | clear |
| Odour: | faintly like esters |

Test method

according to Regulation (EC) No 1907/2006

freeprint ortho® UV

Revision date: 24.07.2018

Product code: 839

Page 5 of 9

| | |
|--|----------------------------------|
| pH-Value: | not determined |
| Changes in the physical state | |
| Melting point: | not determined |
| Initial boiling point and boiling range: | not determined |
| Flash point: | >100 °C DIN 51755 |
| Flammability | |
| Solid: | not applicable |
| Gas: | not applicable |
| Lower explosion limits: | not determined |
| Upper explosion limits: | not determined |
| Auto-ignition temperature | |
| Solid: | not applicable |
| Gas: | not applicable |
| Decomposition temperature: | >=190 °C |
| Oxidizing properties | |
| Not oxidizing. | |
| Vapour pressure: (at 20 °C) | <1 hPa |
| Density (at 20 °C): | 1,09 g/cm ³ DIN 51757 |
| Water solubility: | insoluble |
| Solubility in other solvents | |
| not determined | |
| Partition coefficient: | not determined |
| Vapour density: | not determined |
| Evaporation rate: | not determined |
| 9.2. Other information | |
| Solid content: | not determined |

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

Reacts with : strong oxidising agents, strong alkaline or acidic materials.

10.4. Conditions to avoid

Ultra-violet lighth and daylighth initiate polymerisation of the product. Therefore keep only in tightly closed containers away from any sources of lighth at 15°C - 28°C / 59°F - 82 °F.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

according to Regulation (EC) No 1907/2006

freeprint ortho® UV

Revision date: 24.07.2018

Product code: 839

Page 6 of 9

Acute toxicity

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

| CAS No | Chemical name | | | | |
|------------|---|------------------|---------|----------|--------|
| | Exposure route | Dose | Species | Source | Method |
| 27813-02-1 | Hydroxy propyl methacrylate | | | | |
| | oral | LD50 >2000 mg/kg | Rat | OECD 401 | |
| | dermal | LD50 >5000 mg/kg | Rabbit | | |
| 75980-60-8 | diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide | | | | |
| | oral | LD50 >5000 mg/kg | Rat | | |
| | dermal | LD50 >2000 mg/kg | Rat | | |
| 868-77-9 | 2-hydroxyethyl methacrylate | | | | |
| | oral | LD50 5050 mg/kg | Rat | | |

Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

Sensitising effects

May cause an allergic skin reaction. (isopropylidenediphenol peg-2 dimethacrylate; Urethane Dimethacrylate; Hydroxy propyl methacrylate; tetrahydrofurfuryl methacrylate THFMA purified grade; diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide; 2-hydroxyethyl methacrylate)

Carcinogenic/mutagenic/toxic effects for reproduction

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

STOT-single exposure

May cause respiratory irritation. (isopropylidenediphenol peg-2 dimethacrylate)

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.

Additional information on tests

This mixture is classified as hazardous according to regulation (EC) No. 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

The product is not: Ecotoxic.

according to Regulation (EC) No 1907/2006

freeprint ortho® UV

Revision date: 24.07.2018

Product code: 839

Page 7 of 9

| CAS No | Chemical name | | | | | |
|------------|--|------------------|-----------|---------------------------------|----------|--------|
| | Aquatic toxicity | Dose | [h] [d] | Species | Source | Method |
| 27813-02-1 | Hydroxy propyl methacrylate | | | | | |
| | Acute fish toxicity | LC50 493 mg/l | 96 h | Leuciscus idus (golden orfe) | | |
| | Acute algae toxicity | ErC50 >97,2 mg/l | 72 h | Pseudokirchneriella subcapitata | OECD 201 | |
| | Acute crustacea toxicity | EC50 380 mg/l | 48 h | Daphnia magna (Big water flea) | OECD 202 | |
| 2455-24-5 | tetrahydrofurfuryl methacrylate THFMA purified grade | | | | | |
| | Acute fish toxicity | LC50 34,7 mg/l | 96 h | | | |
| 75980-60-8 | diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide | | | | | |
| | Acute algae toxicity | ErC50 >2,01 mg/l | 72 h | Scenedesmus subspicatus | | |
| | Acute crustacea toxicity | EC50 3,53 mg/l | 48 h | Daphnia magna (Big water flea) | | |
| | Acute bacteria toxicity | (>1000 mg/l) | 3 h | Activated sludge | | |
| 868-77-9 | 2-hydroxyethyl methacrylate | | | | | |
| | Acute fish toxicity | LC50 227 mg/l | 96 h | Pimephales promelas | | |

12.2. Persistence and degradability

The product has not been tested.

| CAS No | Chemical name | | | |
|------------|--|-------|----|--------|
| | Method | Value | d | Source |
| | Evaluation | | | |
| 72829-09-5 | 1,12-Dodecanediol Dimethacrylate | | | |
| | OECD 301C/ ISO 9408/ EEC 92/69/V, C.4-F | 90 % | 28 | |
| 27813-02-1 | Hydroxy propyl methacrylate | | | |
| | OECD | 94% | 28 | |
| | Readily biodegradable (according to OECD criteria). | | | |
| 75980-60-8 | diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide | | | |
| | | 0-10% | 28 | |
| | Not readily biodegradable (according to OECD criteria) | | | |
| 868-77-9 | 2-hydroxyethyl methacrylate | | | |
| | 84 | % | 28 | |
| | Leicht biologisch abbaubar | | | |

12.3. Bioaccumulative potential

The product has not been tested.

Partition coefficient n-octanol/water

| CAS No | Chemical name | Log Pow |
|------------|---|---------|
| 27813-02-1 | Hydroxy propyl methacrylate | 0,97 |
| 75980-60-8 | diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide | 3,1 |
| 868-77-9 | 2-hydroxyethyl methacrylate | 0,47 |

BCF

| CAS No | Chemical name | BCF | Species | Source |
|------------|---|-------|-------------------------------|--------|
| 72829-09-5 | 1,12-Dodecanediol Dimethacrylate | 1230 | | |
| 75980-60-8 | diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide | 47-55 | Cyprinus carpio (Common Carp) | |

according to Regulation (EC) No 1907/2006

freeprint ortho® UV

Revision date: 24.07.2018

Product code: 839

Page 8 of 9

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

Not identified as PBT/ vPvB substances

12.6. Other adverse effects

No information available.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Advice on disposal**

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

Contaminated packaging

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

SECTION 14: Transport information**Land transport (ADR/RID)****14.1. UN number:**

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)**14.1. UN number:**

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Marine transport (IMDG)**14.1. UN number:**

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)**14.1. UN number:**

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

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

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Safety Data Sheet

according to Regulation (EC) No 1907/2006

freeprint ortho® UV

Revision date: 24.07.2018

Product code: 839

Page 9 of 9

National regulatory information

Employment restrictions: Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC).
 Water contaminating class (D): 3 - highly water contaminating
 Skin resorption/Sensitization: Causes allergic hypersensitivity reactions.

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

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 Harmonized 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
 LC50: Lethal concentration, 50%
 LD50: Lethal dose, 50%

Classification for mixtures and used evaluation method according to Regulation (EC) No. 1272/2008 [CLP]

| Classification | Classification procedure |
|---------------------|--------------------------|
| Skin Irrit. 2; H315 | Calculation method |
| Eye Irrit. 2; H319 | Calculation method |
| Skin Sens. 1A; H317 | Calculation method |
| STOT SE 3; H335 | Calculation method |

Relevant H and EUH statements (number and full text)

H315 Causes skin irritation.
 H317 May cause an allergic skin reaction.
 H319 Causes serious eye irritation.
 H335 May cause respiratory irritation.
 H361f Suspected of damaging fertility.
 H411 Toxic to aquatic life with long lasting effects.

Further Information

The information is based on present level of our knowledge. It does not, however, give assurances of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)