

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

Printing date 18.05.2020

Revision: 23.05.2019

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

- **Product identifier**
- **Trade name:** Opal™ Bond™ MV
- **Article number:** 71025
- **Index number:** SDS 368-001.05
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Orthodontic Adhesive
- **Application of the substance / the mixture** Professional Orthodontic Adhesive
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ultradent Products Inc.
505 W. Ultradent Drive (10200 S)
South Jordan, UT 84095-3942
USA
onlineordersupport@ultradent.com
- **EC Responsible Person**
Ultradent Products GmbH
Am Westhoyer Berg 30
51149 Cologne Germany
Email: infoDE@ultradent.com
Emergency Phone: +49(0)2203-35-92-0
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

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



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

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**
Diurethane Dimethacrylate
Triethylene Glycol Dimethacrylate
2-Hydroxyethyl Methacrylate
- **Hazard statements**
H317 May cause an allergic skin reaction.

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- **Precautionary statements**

- P101 *If medical advice is needed, have product container or label at hand.*
- P102 *Keep out of reach of children.*
- P103 *Read label before use.*
- P261 *Avoid breathing dust/fume/gas/mist/vapours/spray.*
- P272 *Contaminated work clothing should not be allowed out of the workplace.*
- P280 *Wear protective gloves.*
- P302+P352 *IF ON SKIN: Wash with plenty of water.*
- P362+P364 *Take off contaminated clothing and wash it before reuse.*
- P333+P313 *If skin irritation or rash occurs: Get medical advice/attention.*
- P321 *Specific treatment (see on this label).*
- P501 *Dispose of contents/container in accordance with local/regional/national/international regulations.*

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterisation: Mixtures**

- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

| | | |
|-------------------|---|-----------|
| CAS: 72869-86-4 | Diurethane Dimethacrylate | >2.5-≤10% |
| EINECS: 276-957-5 | ⚠ Skin Sens. 1, H317 | |
| CAS: 1344-28-1 | Aluminium Oxide | >2.5-≤10% |
| EINECS: 215-691-6 | substance with a Community workplace exposure limit | |
| CAS: 14808-60-7 | Silica Glass | >2.5-≤10% |
| EINECS: 238-878-4 | ⚠ Acute Tox. 4, H332; Skin Irrit. 2, H315 | |
| CAS: 109-16-0 | Triethylene Glycol Dimethacrylate | ≤2.5% |
| EINECS: 203-652-6 | ⚠ Skin Sens. 1, H317 | |
| CAS: 868-77-9 | 2-Hydroxyethyl Methacrylate | 0-≤2.5% |
| EINECS: 212-782-2 | ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 | |

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

4 First aid measures

- **Description of first aid measures**

- **General information:** Immediately remove any clothing soiled by the product.

- **After inhalation:**

This product is a thick paste, therefore inhalation is extremely unlikely.

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. If symptoms persist, consult a doctor.

- **After swallowing:** Do not induce vomiting. Seek medical help if necessary.

- **Information for doctor:**

- **Most important symptoms and effects, both acute and delayed** No further relevant information available.

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- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
Foam, dry chemical, carbon dioxide
Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters:**
- **Protective equipment:**
Wear self-contained respiratory protective device.
Wear fully protective suit.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **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.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling:** Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Protect from exposure to the light.
Protect from heat
See product labelling.
- **Specific end use(s)** Professional Orthodontic Adhesive

8 Exposure controls/personal protection

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

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- **Control parameters**

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

| | |
|----------------------------------|---|
| 1344-28-1 Aluminium Oxide | |
| WEL (Great Britain) | Long-term value: 10* 4** mg/m ³ *inhalable dust **respirable dust |

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

- **Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**

Avoid contact with the eyes and skin.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

- **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

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

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

The selection of 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 breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:** Not required.

- **Body protection:** Protective work clothing

9 Physical and chemical properties

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

- **General Information**

- **Appearance:**

Form: Paste

Colour: Whitish

- **Odour:** Acrylic

- **Odour threshold:** Not determined.

- **pH-value:** Not applicable (non-aqueous)

- **Change in condition**

Melting point/freezing point: Undetermined.

Initial boiling point and boiling range: Undetermined.

- **Flash point:** Not applicable.

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| | |
|--|---|
| · Flammability (solid, gas): | Not determined. |
| · 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. |
| · Vapour pressure: | Not applicable. |
| · Density at 20 °C: | 2.03 g/cm ³ |
| · Relative density | Not determined. |
| · Vapour density | Not applicable. |
| · Evaporation rate | Not applicable. |
| · Solubility in / Miscibility with water: | Insoluble. |
| · Partition coefficient: n-octanol/water: | Not determined. |
| · Viscosity: | |
| Dynamic: | Not applicable. |
| Kinematic: | Not applicable. |
| · Solvent content: | |
| VOC (EC) | <1 % |
| Solids content: | <100.0 % |
| · Other information | No further relevant information available. |

10 Stability and reactivity

- **Reactivity Stable**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:**
 - Light
 - Ignition sources
 - Flames
 - Heat
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

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

| | | |
|--|----------|----------------|
| · LD/LC50 values relevant for classification: | | |
| ATE (Acute Toxicity Estimates) | | |
| Inhalative | LC50/4 h | 22.8-37.9 mg/l |

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| | | |
|---|---------------------|-------------------------------------|
| 72869-86-4 Diurethane Dimethacrylate | | |
| Oral | LD50 | >5,000 mg/kg (rat) |
| 1344-28-1 Aluminium Oxide | | |
| Oral | LD50 | >5,000 mg/kg (rat) |
| 109-16-0 Triethylene Glycol Dimethacrylate | | |
| Oral | LD50 | >5,000 mg/kg (rat) |
| | LC50 Fish | 16.4 mg/l (Fish) (Toxicity to fish) |
| Dermal | LD50 | >2,000 mg/kg (mouse) |
| 868-77-9 2-Hydroxyethyl Methacrylate | | |
| Oral | LD50 | 3,275 mg/kg (mouse) |
| | | >5,000 mg/kg (rat) |
| | LC50 Fish | >100 mg/l (Fish) |
| Dermal | LD50 | >3,000 mg/kg (rabbit) |
| | LC50(Daphnia magna) | 24.1 mg/l (daphnia) |

- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **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** 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.

12 Ecological information

- **Toxicity**

| | |
|---|---|
| · Aquatic toxicity: | |
| 72869-86-4 Diurethane Dimethacrylate | |
| Biodegradability | 28 days (Aerobic) (Biodegradability testing) |
| EC50 | >0.6 mg/l (Algae) (Toxicity to algae) |
| | >1.2 mg/l (daphnia) (Toxicity to aquatic invertebrates) |
| 109-16-0 Triethylene Glycol Dimethacrylate | |
| Biodegradability | 28 days (Aerobic) (Biodegradability testing) |
| Aqua toxicity | 32 mg/l (daphnia) (No Observed Effect Concentration) |
| EC50 | >100 mg/l (Algae) (Toxicity to algae) |
| 868-77-9 2-Hydroxyethyl Methacrylate | |
| EC50 | 345 mg/l (Algae) |

- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.

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- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation** Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

| | |
|---|-----------------|
| · UN-Number | |
| · ADR, ADN, IMDG, IATA | not regulated |
| · UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | not regulated |
| · Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | not regulated |
| · Packing group | |
| · ADR, IMDG, IATA | not regulated |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | not regulated |

15 Regulatory information

- **Chemical safety assessment:**
Device is biocompatible when used as directed by dental professionals per ISO 10993-1

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.

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*H319 Causes serious eye irritation.**H332 Harmful if inhaled.**· Department issuing SDS: Regulatory Affairs**· Contact: Customer Service**· 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)**VOC: Volatile Organic Compounds (USA, EU)**LC50: Lethal concentration, 50 percent**LD50: Lethal dose, 50 percent**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**Acute Tox. 4: Acute toxicity - inhalation – Category 4**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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