

Safety data sheet according to UK REACH

Printing date 23.07.2025

Version number 1

Revision: 23.07.2025

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

· **Product identifier**

· **Trade name:** Opal™ Seal™

· **Article number:** SDS 265-001.10R01, 71022, 50159, 50176, 500061, 500061-JP, 500062, 500063

· **Relevant identified uses of the substance or mixture and uses advised against**
Professionelle Kieferorthopädische Grundierung und Versiegelung

· **Application of the substance / the mixture** *Professional Orthodontic Primer and Sealant*

· **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
 (800) 552-5512*

*EC Responsible Person
 Ultradent Products GmbH
 Am Westhover Berg 30
 51149 Cologne Germany
 Email: infoDE@ultradent.com
 Office Phone: +49(0)2203-35-92-0*

· **Further information obtainable from:** *Customer Service*

· **Emergency telephone number:**

*CHEMTREC (NORTH AMERICA) : +1 (800) 424-9300
 (INTERNATIONAL) : +(703) 527-3887*

2 Hazards identification

· **Classification of the substance or mixture**

· **Classification according to Regulation (EC) No 1272/2008**



flame

Flam. Liq. 3 H226 Flammable liquid and vapour.



health hazard

Repr. 1B H360 May damage fertility or the unborn child.



corrosion

Skin Corr. 1A H314 Causes severe skin burns and eye damage.

Eye Dam. 1 H318 Causes serious eye damage.

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

STOT SE 3 H335 May cause respiratory irritation.

· **Label elements**

· **Labelling according to Regulation (EC) No 1272/2008** Void

· **Hazard pictograms** GHS02, GHS05, GHS07, GHS08

· **Signal word** Danger

· **Hazard-determining components of labelling:**

Methacrylic Acid

Ethyl-4-Dimethylamino Benzoate

Trade Secret

Organophosphine Oxide

· **Hazard statements**

H226 Flammable liquid and vapour.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H360 May damage fertility or the unborn child.

H335 May cause respiratory irritation.

· **Precautionary statements**

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read carefully and follow all instructions.

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

P321 Specific treatment (see on this label).

P362+P364 Take off contaminated clothing and wash it before reuse.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

3 Composition/information on ingredients

· **Mixtures**

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

· **Dangerous components:**

CAS: 27813-02-1	Hydroxypropyl Methacrylate	>10-≤25%
EINECS: 248-666-3	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	
CAS: 64-17-5	Ethyl Alcohol	1-10%
EINECS: 200-578-6	⚠ Flam. Liq. 2, H225	

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CAS: 1830-78-0 EINECS: 217-388-4	Glycerol Dimethacrylate ⚠ Skin Irrit. 2, H315; STOT SE 3, H335	≥1-<10%
CAS: 79-41-4 EINECS: 201-204-4	Methacrylic Acid ⚠ Acute Tox. 3, H311; ⚠ Skin Corr. 1A, H314; Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302; Acute Tox. 4, H332; STOT SE 3, H335 Specific concentration limit: STOT SE 3; H335: C ≥ 1 %	≥5-≤10%
	Trade Secret ⚠ Skin Corr. 1A, H314	≥1-<5%
CAS: 10287-53-3 EINECS: 233-634-3	Ethyl-4-Dimethylamino Benzoate ⚠ Repr. 1B, H360; ⚠ Aquatic Chronic 2, H411	≥0.3-<2.5%
	Organophosphine Oxide ⚠ Skin Sens. 1A, H317; Aquatic Chronic 4, H413	≥0.1-<1%

· **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:**
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.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:** Drink plenty of water and provide fresh air. Call for a doctor immediately.
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

- **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
- **Special hazards arising from the substance or mixture**
During heating or in case of fire poisonous gases are produced.
- **Advice for firefighters:**
- **Protective equipment:** Mouth respiratory protective device.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Mount respiratory protective device.
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:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Use neutralising agent.
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.

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- **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

- **Precautions for safe handling:**
- Ensure good ventilation/exhaustion at the workplace.
- Open and handle receptacle with care.
- Prevent formation of aerosols.
- **Information about fire - and explosion protection:**
- Keep ignition sources away - Do not smoke.
- Protect against electrostatic charges.
- Keep respiratory protective device available.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
- See product labelling.
- Keep container tightly sealed.
- **Specific end use(s)** Professional Orthodontic Primer and Sealant

8 Exposure controls/personal protection

- **Control parameters**

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

64-17-5 Ethyl Alcohol

WEL	Long-term value: 1920 mg/m ³ , 1000 ppm
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79-41-4 Methacrylic Acid

WEL	Short-term value: 143 mg/m ³ , 40 ppm
	Long-term value: 72 mg/m ³ , 20 ppm

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

- **Exposure controls**

- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as 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.
- 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.

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· Hand protection



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/face protection



Tightly sealed goggles

· Body protection: Protective work clothing

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Physical state	Fluid
· Colour:	Yellow
· Odour:	Acrylic
· Odour threshold:	Not determined.
· Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling point and boiling range	Undetermined.
· Flammability	Flammable.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	37 °C
· Decomposition temperature:	Not determined.
· pH	Not applicable (non-aqueous)
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Not miscible or difficult to mix.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not determined.

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· Other information	
· Appearance:	
· Form:	Viscous Liquid
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· Change in condition	
· Evaporation rate	Not determined.
· Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Flammable liquid and vapour.
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **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:** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

ATE (Acute Toxicity Estimates)

Oral	LD50	17,667 mg/kg
Dermal	LD50	8,333 mg/kg (rabbit)
Inhalative	LC50/4 h	118 mg/l

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64-17-5 Ethyl Alcohol

Oral	LD50	5,600 mg/kg (guinea pig)
		3,400 mg/kg (mouse)
		7,060 mg/kg (rat)
Inhalative	LC50 Fish	>10,000 mg/l (Fish)
	LC50/4 h	39 mg/l (mouse) 20,000 mg/l (rat)

79-41-4 Methacrylic Acid

Oral	LD50	1,250 mg/kg (mouse)
		1,060 mg/kg (rat)
		1,200 mg/kg (rabbit)
Dermal	LC50 Fish	86 mg/l (Fish)
	LD50	1,000 mg/kg (guinea pig) 500 mg/kg (rabbit)
Inhalative	LC50/4 h	7.1 mg/l (rat)

Organophosphine Oxide

Oral	LD50	>2,000 mg/kg (rat)
	LC50 Fish	>0.09 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>2,000 mg/kg (rat)

- **Primary irritant effect:**
- **Skin corrosion/irritation** Causes severe skin burns and eye damage.
- **Serious eye damage/irritation** Causes serious eye damage.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **Reproductive toxicity** May damage fertility or the unborn child.
- **STOT-single exposure** May cause respiratory irritation.
- **Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**

- **Aquatic toxicity:**

64-17-5 Ethyl Alcohol

Algae Toxicity	1,000 mg/l (Algae)
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79-41-4 Methacrylic Acid

EC50	17,000 mg/kg (Algae) <180 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
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Organophosphine Oxide

EC50 (static)	>1.175 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
Aqua toxicity	≥0.008 mg/l (daphnia) (Daphnia Magna Reproduction Test)
Toxicity to Aquatic Plants (static)	>0.26 mg/l (Plant) (Toxicity to algae)

- **Persistence and degradability** No further relevant information available.
- **Bioaccumulative potential** No further relevant information available.

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- **Mobility in soil** No further relevant information available.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Endocrine disrupting properties** The product does not contain substances with endocrine disrupting properties.
- **Other adverse effects**
- **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.
Must not reach sewage water or drainage ditch undiluted or unneutralised.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
Dispose of contents/container in accordance with international, federal, state, and local regulations.
- **Uncleaned packaging:**
- **Recommendation:** *Disposal must be made according to official regulations.*

14 Transport information

- | | |
|---|---|
| <ul style="list-style-type: none"> · UN number or ID number · ADR, IMDG, IATA | UN2924 |
| <ul style="list-style-type: none"> · UN proper shipping name · ADR · IMDG, IATA | 2924 FLAMMABLE LIQUID, CORROSIVE, N.O.S.
(METHACRYLIC ACID, STABILIZED, Ethyl Alcohol)
FLAMMABLE LIQUID, CORROSIVE, N.O.S. (METHACRYLIC
ACID, STABILIZED, Ethyl Alcohol) |
| <ul style="list-style-type: none"> · Transport hazard class(es) · ADR | <div style="display: flex; justify-content: space-around; align-items: center;">   </div> |
| <ul style="list-style-type: none"> · Class · Label | 3 Flammable liquids.
3+8 |
| <ul style="list-style-type: none"> · IMDG | <div style="display: flex; justify-content: space-around; align-items: center;">   </div> |
| <ul style="list-style-type: none"> · Class | 3 Flammable liquids. |

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· Label	3/8
· IATA	
	
· Class	3 Flammable liquids.
· Label	3 (8)
· Packing group	
· ADR, IMDG, IATA	II
· Environmental hazards:	Not applicable.
· Special precautions for user	Warning: Flammable liquids.
· Hazard identification number (Kemler code):	38
· EMS Number:	F-E,S-C
· Stowage Category	B
· Stowage Code	SW2 Clear of living quarters.
· Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category	2
· Tunnel restriction code	D/E
· IMDG	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 2924 FLAMMABLE LIQUID, CORROSIVE, N.O.S. (METHACRYLIC ACID, STABILIZED, ETHYL ALCOHOL), 3 (8), II

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **Poisons Act**

· **Regulated explosives precursors**

None of the ingredients is listed.

· **Regulated poisons**

None of the ingredients is listed.

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· Reportable explosives precursors

None of the ingredients is listed.

· Reportable poisons

None of the ingredients is listed.

· Directive 2012/18/EU

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **Seveso category P5c** FLAMMABLE LIQUIDS

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5,000 t

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50,000 t

· 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 from Section 3

H225 Highly flammable liquid and vapour.

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H360 May damage fertility or the unborn child.

H411 Toxic to aquatic life with long lasting effects.

H413 May cause long lasting harmful effects to aquatic life.

· **Department issuing SDS:** Environmental, Health, and Safety

· **Contact:** Customer Service

· Abbreviations and acronyms:

ADR: Accord relatif au transport international 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

NIOSH: National Institute for Occupational Safety

ATE: Acute toxicity estimate values

Flam. Liq. 2: Flammable liquids – Category 2

Flam. Liq. 3: Flammable liquids – Category 3

Acute Tox. 4: Acute toxicity – Category 4

Acute Tox. 3: Acute toxicity – Category 3

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

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*Skin Sens. 1A: Skin sensitisation – Category 1A**Repr. 1B: Reproductive toxicity – Category 1B**STOT SE 3: Specific target organ toxicity (single exposure) – Category 3**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.*

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