Safety Data Sheet
acc. to OSHA HCS

Printing date 09/20/2021 Reviewed on 04/23/2020

1 Identification

· **Product identifier**

· **Trade name: Opal™ Seal™**

· **Article number:** SDS 265-001.09, OS/71022
· **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

· **Information department:** Customer Service
· **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) :(800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) identification

· **Classification of the substance or mixture**

GHS02 Flame

Flam. Liq. 3 H226 Flammable liquid and vapor.

GHS05 Corrosion

Skin Corr. 1A H314 Causes severe skin burns and eye damage.
Eye Dam. 1 H318 Causes serious eye damage.

GHS07

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

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** GHS02, GHS05, GHS07
· **Signal word** Danger

· **Health Hazard-determining components of labeling:**
Methacrylic Acid
Hydroxypropyl Methacrylate
Trade Secret
Organophosphine Oxide
· **Hazard statements**
Flammable liquid and vapor.

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Causes severe skin burns and eye damage.
May cause an allergic skin reaction.

· **Precautionary statements**

P210	Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P233	Keep container tightly closed.
P240	Ground/bond container and receiving equipment.
P241	Use explosion-proof electrical/ventilating/lighting/equipment.
P242	Use only non-sparking tools.
P243	Take precautionary measures against static discharge.
P260	Do not breathe dusts or mists.
P264	Wash thoroughly after handling.
P272	Contaminated work clothing must not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331	If swallowed: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353	If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
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).
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P363	Wash contaminated clothing before reuse.
P370+P378	In case of fire: Use for extinction: CO2, powder or water spray.
P403+P235	Store in a well-ventilated place. Keep cool.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**
· **NFPA ratings (scale 0 - 4)**

Health = 3
Fire = 3
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

Health = *3
Fire = 3
Reactivity = 0

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

27813-02-1	Hydroxypropyl Methacrylate Skin Irrit. 2, H315; Eye Irrit. 2A, H319; Skin Sens. 1, H317	>10-≤25%
64-17-5	Ethyl Alcohol Flam. Liq. 2, H225	1-10%
79-41-4	Methacrylic Acid Acute Tox. 3, H331; Skin Corr. 1A, H314; Eye Dam. 1, H318; Acute Tox. 4, H302; Acute Tox. 4, H312; Flam. Liq. 4, H227	≥5-≤10%

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2530-85-0	Silane Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	≥0-<10%
	Trade Secret Skin Corr. 1A, H314	≥1-<5%
162881-26-7	Organophosphine Oxide Skin Sens. 1, H317	≥0.1-<1%

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 copious amounts of water and provide fresh air. Immediately call a doctor.
· **Information for doctor:**
· **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 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:**
CO_2, extinguishing 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 neutralizing agent.
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.

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7 Handling and storage

· **Handling:**
· **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
· **Information about protection against explosions and fires:**
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 receptacle tightly sealed.
· **Specific end use(s)** Professional Orthodontic Primer and Sealant

8 Exposure controls/personal protection

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

· **Control parameters**
· **Components with limit values that require monitoring at the workplace:**
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.
At this time, the other constituents have no known exposure limits.

64-17-5 Ethyl Alcohol	
PEL	Long-term value: 1900 mg/m³, 1000 ppm
REL	Long-term value: 1900 mg/m³, 1000 ppm
STEL	Short-term value: 1000 mg/m³
TLV	Short-term value: 1880 mg/m³, 1000 ppm
TWA	Short-term value: 1900 mg/m³
79-41-4 Methacrylic Acid	
REL	Long-term value: 70 mg/m³, 20 ppm Skin
TLV	Long-term value: 70 mg/m³, 20 ppm

· **Additional information:** The lists that were valid during the creation were used as basis.

· **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.
Avoid contact with the eyes and skin.
· **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

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· **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 is based 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:**

Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Viscous
Color:	Yellow
· **Odor:**	Acrylic
· **Odor threshold:**	Not determined.
· **pH-value:**	Not applicable (non-aqueous)
· **Change in condition**	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined
· **Flash point:**	37 °C
· **Flammability (solid, gaseous):**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.

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· **Vapor pressure:**	Not determined.
· **Density:**	Not determined
· **Relative density**	Not determined
· **Vapor 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:**	
VOC content:	14.50 % 145.0 g/l / 1.21 lb/gal
VOC (EC)	14.50 %
Solids content:	<50.0 %
· **Other information**	No further relevant information available.

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 toxicological effects**
· **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**

ATE (Acute Toxicity Estimate)

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

64-17-5 Ethyl Alcohol

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

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		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)
	LC50 Fish	86 mg/l (Fish)
Dermal	LD50	1,000 mg/kg (Guinea pig)
		500 mg/kg (rabbit)
Inhalative	LC50/4 h	7.1 mg/l (rat)
162881-26-7 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:**
· **on the skin:** Strong caustic effect on skin and mucous membranes.
· **on the eye:**
Strong caustic effect.
Strong irritant with the danger of severe eye injury.
· **Sensitization:** Sensitization possible through skin contact.
· **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Corrosive
Irritant
Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**		
64-17-5	Ethyl Alcohol	1

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**	
64-17-5 Ethyl Alcohol	
Algae Toxicity	1,000 mg/l (Algae)
79-41-4 Methacrylic Acid	
EC50	17,000 mg/kg (Algae)
	<180 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
162881-26-7 Organophosphine Oxide	
EC50 (static)	>1.175 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
Aqua toxicity	≥0.008 mg/l (daphnia) (Daphnia Magna Reproduction Test)

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Toxicity to Aquatic Plants (static)	>0.26 mg/l (Plant) (Toxicity to algae)

· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (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 bodies of water or drainage ditch undiluted or unneutralized.
· **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:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· **UN-Number**	
· **DOT, IMDG, IATA**	UN2924
· **UN proper shipping name**	
· **DOT**	Flammable liquids, corrosive, n.o.s.
· **IMDG, IATA**	FLAMMABLE LIQUID, CORROSIVE, N.O.S. (METHACRYLIC ACID, STABILIZED, Ethyl Alcohol)

· **Transport hazard class(es)**

· **DOT**

· **Class**	3 Flammable liquids
· **Label**	3, 8

· **IMDG**

· **Class**	3 Flammable liquids

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· **Label**	3/8
· **IATA**	
	
· **Class**	3 Flammable liquids
· **Label**	3 (8)
· **Packing group**	
· **DOT, 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.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not Applicable.
· **Transport/Additional information:**	
· **DOT**	
· **Quantity limitations**	On passenger aircraft/rail: 1 L On cargo aircraft only: 5 L
· **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**
No further relevant information available.

· **Sara**

· **Section 355 (extremely hazardous substances):**

Trade Secret

· **Section 313 (Specific toxic chemical listings):**

1344-28-1	Aluminium Oxide

· **TSCA (Toxic Substances Control Act):**

27813-02-1	Hydroxypropyl Methacrylate	ACTIVE
64-17-5	Ethyl Alcohol	ACTIVE
79-41-4	Methacrylic Acid	ACTIVE

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2530-85-0	Silane	ACTIVE
	Trade Secret	ACTIVE
162881-26-7	Organophosphine Oxide	ACTIVE

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

64-17-5	Ethyl Alcohol

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **ACGIH Carcinogenicity (American Conference of Governmental Industrial Hygienists)**

64-17-5	Ethyl Alcohol	A3
1344-28-1	Aluminium Oxide	A4

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

None of the ingredients is listed.

· **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.

· **Department issuing SDS:** Environmental, Health, and Safety
· **Contact:** Customer Service
· **Date of preparation / last revision** 09/20/2021 / -
· **Abbreviations and acronyms:**
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
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)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
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
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit

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Flam. Liq. 2: Flammable liquids – Category 2
Flam. Liq. 3: Flammable liquids – Category 3
Flam. Liq. 4: Flammable liquids – Category 4
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. 2A: Serious eye damage/eye irritation – Category 2A
Skin Sens. 1: Skin sensitisation – Category 1
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3