

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

Printing date 18.04.2019

Revision: 17.04.2019

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

· **Product identifier**

· **Trade name:** Peak™ Universal Bond

· **Article number:** 71057

· **Index number:** SDS 206-001.11

· **Relevant identified uses of the substance or mixture and uses advised against** Professional Dental Adhesive

· **Application of the substance / the mixture** Professional Dental 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:**

During normal opening times: +1 (801) 553-4862

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**



GHS02 flame

Flam. Liq. 3 H226

Flammable liquid and vapour.



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.

STOT SE 3

H335-H336

May cause respiratory irritation. May cause drowsiness or dizziness.

Ozone 1

H420

Harms public health and the environment by destroying ozone in the upper atmosphere

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- **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** GHS02, GHS05, GHS07

- **Signal word** Danger

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

Methacrylic Acid

2-Hydroxyethyl Methacrylate

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.

H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.

H420 Harms public health and the environment by destroying ozone in the upper atmosphere

- **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.

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/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.

P405 Store locked up.

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: 64-17-5	Ethyl Alcohol	>10-≤20%
EINECS: 200-578-6	⚠ Flam. Liq. 2, H225	
CAS: 868-77-9	2-Hydroxyethyl Methacrylate	>10-≤25%
EINECS: 212-782-2	⚠ Skin Irrit. 2, H315; ⚠ Eye Irrit. 2, H319; ⚠ Skin Sens. 1, H317	
CAS: 79-41-4	Methacrylic Acid	≤6%
EINECS: 201-204-4	⚠ Acute Tox. 3, H331; ⚠ Skin Corr. 1A, H314; ⚠ Acute Tox. 4, H302; ⚠ Acute Tox. 4, H312	

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	Trade Secret	>2.5-≤10%
	⚠ Skin Corr. 1A, H314	
CAS: 162881-26-7 ELINCS: 423-340-5	Organophosphine Oxide	≤2.5%
	⚠ Skin Sens. 1, H317; Aquatic Chronic 4, H413	
CAS: 128-37-0 EINECS: 204-881-4	Butylated hydroxytoluene	≤2.5%
	⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410; ⚠ Acute Tox. 4, H302	
CAS: 56-95-1 EINECS: 200-302-4	Chlorhexidine Diacetate	≤0.2%
	⚠ Acute Tox. 4, H302	

· **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.
- **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 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Foam, dry chemical, carbon dioxide
- **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:**
General: Evacuate all personnel; use protective equipment for fire fighting. Use self-contained breathing apparatus when the product is involved in fire.
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 item 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

- **Handling:**
- **Precautions for safe handling:** Keep away from heat and direct sunlight.
- **Information about fire - and explosion protection:**
- Keep ignition sources away - Do not smoke.
- Protect against electrostatic charges.
- **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 Dental Adhesive

8 Exposure controls/personal protection

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

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

64-17-5 Ethyl Alcohol

WEL (Great Britain) Long-term value: 1920 mg/m³, 1000 ppm

79-41-4 Methacrylic Acid

WEL (Great Britain) Short-term value: 143 mg/m³, 40 ppm
Long-term value: 72 mg/m³, 20 ppm

128-37-0 Butylated hydroxytoluene

WEL (Great Britain) Long-term value: 10 mg/m³

- **Additional information:** The lists valid during the making 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.
- **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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· **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:**

Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**· **General Information**· **Appearance:**

Form:	Liquid
Colour:	Light yellow
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:	60 °C

· **Flash point:** 24 °C

· **Flammability (solid, gas):** Not applicable.

· **Ignition temperature:** 425 °C

· **Decomposition temperature:** Not determined.

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

· **Explosion limits:**

Lower:	3.5 Vol %
Upper:	15 Vol %

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· Vapour pressure at 20 °C:	59 hPa
· Density at 20 °C:	1.1 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:	
VOC (EC)	<20.00 %
Solids content:	<15.0 %
· 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** 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
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)

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868-77-9 2-Hydroxyethyl Methacrylate		
Oral	LD50	3,275 mg/kg (mouse) >5,000 mg/kg (rat)
Dermal	LC50 Fish	>100 mg/l (Fish)
	LD50	>3,000 mg/kg (rabbit)
	LC50(Daphnia magna)	24.1 mg/l (daphnia)
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)
162881-26-7 Organophosphine Oxide		
Oral	LD50	>2,000 mg/kg (rat)
Dermal	LC50 Fish	>0.09 mg/l (Fish) (Toxicity to fish)
	LD50	>2,000 mg/kg (rat)
56-95-1 Chlorhexidine Diacetate		
Oral	LD50	2,000 mg/kg (mouse) 1,180 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rabbit)
128-37-0 Butylated hydroxytoluene		
Oral	LD50	10,700 mg/kg (Guinea pig) 1,040 mg/kg (mouse) 890 mg/kg (rat)
Dermal	LC50 Fish	5.3 mg/l (Fish)
	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.
- **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**
May cause respiratory irritation. May cause drowsiness or dizziness.
- **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.

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12 Ecological information

- **Toxicity**

· Aquatic toxicity:	
64-17-5 Ethyl Alcohol	
Algae Toxicity	1,000 mg/l (Algae)
868-77-9 2-Hydroxyethyl Methacrylate	
EC50	345 mg/l (Algae)
79-41-4 Methacrylic Acid	
EC50	<180 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
EC50	45 mg/l (Algae) (Toxicity to algae)
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)
Toxicity to Aquatic Plants (static)	>0.26 mg/l (Plant) (Toxicity to algae)
128-37-0 Butylated hydroxytoluene	
Aqua toxicity (static)	0.48 mg/l (daphnia) (Toxicity to aquatic invertebrates)

- **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.

- **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.

- **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 together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue	
HP 3	Flammable
HP 8	Corrosive
HP 13	Sensitising
HP 14	Ecotoxic

- **Uncleaned packaging:**

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

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14 Transport information

· UN-Number · ADR, IMDG, IATA	UN2924
· UN proper shipping name · ADR · IMDG, IATA	2924 FLAMMABLE LIQUID, CORROSIVE, N.O.S. (Ethyl Alcohol, METHACRYLIC ACID, STABILIZED) FLAMMABLE LIQUID, CORROSIVE, N.O.S. (Ethyl Alcohol, METHACRYLIC ACID, STABILIZED)
· Transport hazard class(es) · ADR	
	
· Class · Label	3 Flammable liquids. 3+8
· IMDG	
	
· Class · Label	3 Flammable liquids. 3/8
· IATA	
	
· Class · Label	3 Flammable liquids. 3 (8)
· Packing group · ADR, IMDG, IATA	III
· Environmental hazards:	Not applicable.
· Special precautions for user · Danger code (Kemler): · EMS Number: · Segregation groups · Stowage Category · Stowage Code	Warning: Flammable liquids. 38 F-E,S-C Acids A SW2 Clear of living quarters.
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR · Limited quantities (LQ)	5L

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· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· Transport category	3
· Tunnel restriction code	D/E
· IMDG	
· Limited quantities (LQ)	5L
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· UN "Model Regulation":	UN 2924 FLAMMABLE LIQUID, CORROSIVE, N.O.S. (ETHYL ALCOHOL, METHACRYLIC ACID, STABILIZED), 3 (8), III

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **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**
- **REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3**
- **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**
H225 Highly flammable liquid and vapour.
H302 Harmful if swallowed.
H312 Harmful in contact with skin.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H331 Toxic if inhaled.
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: 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

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*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**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**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 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4**Ozone 1: Hazardous to the ozone layer – Category 1*

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