

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

Printing date 29.10.2020

Revision: 18.09.2020

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

- **Product identifier**
- **Trade name:** Peak™ SE Primer, Part 2 of 2
- **Article number:** 15077
- **Index number:** SDS 343-001.04
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Adhesive Primer, Part 2
- **Application of the substance / the mixture** Professional Dental Adhesive Primer, Part 2
- **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**



GHS02 flame

Flam. Liq. 3 H226 Flammable liquid and vapour.

- **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
- **Signal word** Warning
- **Hazard statements**
H226 Flammable liquid and vapour.
- **Precautionary statements**
P101 If medical advice is needed, have product container or label at hand.
P102 Keep out of reach of children.

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- P103 Read label before use.
- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- P233 Keep container tightly closed.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- P370+P378 In case of fire: Use for extinction: CO₂, powder or water spray.
- P403+P235 Store in a well-ventilated place. Keep cool.
- 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-≤25%
EINECS: 200-578-6			

- **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; consult doctor in case of complaints.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.
Wash clothing before reuse. Clean shoes thoroughly before reuse.
- **After eye contact:**
Remove contact lenses, if present. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Call a physician if irritation develops or persists.
- **After swallowing:** If swallowed in large quantities seek medical attention.
- **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:** Water spray, fog, or mist, foam, dry chemical, carbon dioxide
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture** No further relevant information available.

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- **Advice for firefighters:**

General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.

- **Protective equipment:**

Wear fully protective suit.
Wear self-contained respiratory protective device.

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:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

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:**

Avoid heat, sparks, and flames

Avoid contact with eyes, skin, and clothing.

- **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 Primer

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/m ³ , 1000 ppm
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- **Additional information:** The lists valid during the making were used as basis.

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- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Avoid contact with the eyes.
Avoid contact with the eyes and skin.
Avoid contact with clothing
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
- **Respiratory protection:** *Not required.*
- **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:	Clear
Odour:	Alcohol-like
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:** *43 °C*

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

- **Decomposition temperature:** *Not determined.*

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· 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:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not determined.
· Density at 20 °C:	0.971 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:	
Water:	<90 %
VOC (EC)	<20%
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** Stable when stored and handled under recommended conditions.
- **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:**
 - Sparks
 - Flames
 - Heat
 - Direct sunlight
 - Extreme temperature
- **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:		
64-17-5 Ethyl Alcohol		
Oral	LD50	5,600 mg/kg (Guinea pig)
		3,400 mg/kg (mouse)

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Inhalative	LC50 Fish	7,060 mg/kg (rat) >10,000 mg/l (Fish)
	LC50/4 h	39 mg/l (mouse) 20,000 mg/l (rat)

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

64-17-5 Ethyl Alcohol

Algae Toxicity	1,000 mg/l (Algae)
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- **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.
- **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.

- **European waste catalogue**

HP3	Flammable
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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

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14 Transport information

<ul style="list-style-type: none"> · UN-Number · ADR, IMDG, IATA 	<p style="margin: 0;">UN1987</p>
<ul style="list-style-type: none"> · UN proper shipping name · ADR · IMDG, IATA 	<p style="margin: 0;">1987 ALCOHOLS, N.O.S. (Ethyl Alcohol) ALCOHOLS, N.O.S. (Ethyl Alcohol)</p>
<ul style="list-style-type: none"> · Transport hazard class(es) · ADR, IMDG, IATA 	<div style="text-align: center; margin: 10px 0;">  </div>
<ul style="list-style-type: none"> · Class · Label 	<p style="margin: 0;">3 Flammable liquids. 3</p>
<ul style="list-style-type: none"> · Packing group · ADR, IMDG, IATA 	<p style="margin: 0;">III</p>
<ul style="list-style-type: none"> · Environmental hazards: 	<p style="margin: 0;">Not applicable.</p>
<ul style="list-style-type: none"> · Special precautions for user · Hazard identification number (Kemler code): · EMS Number: · Stowage Category 	<p style="margin: 0;">Warning: Flammable liquids. 30 F-E,S-D A</p>
<ul style="list-style-type: none"> · Transport in bulk according to Annex II of Marpol and the IBC Code 	<p style="margin: 0;">Not applicable.</p>
<ul style="list-style-type: none"> · Transport/Additional information: 	
<ul style="list-style-type: none"> · ADR · Limited quantities (LQ) · Excepted quantities (EQ) 	<p style="margin: 0;">5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml</p>
<ul style="list-style-type: none"> · Transport category · Tunnel restriction code 	<p style="margin: 0;">3 D/E</p>
<ul style="list-style-type: none"> · IMDG · Limited quantities (LQ) · Excepted quantities (EQ) 	<p style="margin: 0;">5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml</p>
<ul style="list-style-type: none"> · UN "Model Regulation": 	<p style="margin: 0;">UN 1987 ALCOHOLS, N.O.S. (ETHYL ALCOHOL), 3, III</p>

15 Regulatory information

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

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- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50,000 t
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

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.

- **Relevant phrases**

H225 Highly flammable liquid and vapour.

- **Department issuing SDS:** Environmental, Health & Safety

- **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

Flam. Liq. 2: Flammable liquids – Category 2

Flam. Liq. 3: Flammable liquids – Category 3

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