

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

Printing date 24.03.2020

Revision: 27.03.2019

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

- **Product identifier**
- **Trade name:** Peak™-ZM
- **Article number:** 1006644
- **Index number:** SDS 355-001.09
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Bonding Agent
- **Application of the substance / the mixture** Professional Dental Bonding Agent
- **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. 2 H225 Highly flammable liquid and vapour.



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

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**

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.

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- **Hazard pictograms** GHS02, GHS07
- **Signal word** *Danger*

- **Hazard-determining components of labelling:**
2-Hydroxyethyl Methacrylate
- **Hazard statements**
H225 *Highly flammable liquid and vapour.*
H315 *Causes skin irritation.*
H319 *Causes serious eye irritation.*
H317 *May cause an allergic skin reaction.*
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 label before use.*
P210 *Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.*

P240 *Ground and bond container and receiving equipment.*
P241 *Use explosion-proof [electrical/ventilating/lighting] equipment.*
P242 *Use non-sparking tools.*
P243 *Take action to prevent static discharges.*
P261 *Avoid breathing dust/fume/gas/mist/vapours/spray.*
P264 *Wash thoroughly after handling.*
P271 *Use only outdoors or in a well-ventilated area.*
P272 *Contaminated work clothing should not be allowed out of the workplace.*
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].*
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.*
P312 *Call a POISON CENTER/doctor if you feel unwell.*
P321 *Specific treatment (see on this label).*
P362+P364 *Take off contaminated clothing and wash it before reuse.*
P333+P313 *If skin irritation or rash occurs: Get medical advice/attention.*
P337+P313 *If eye irritation persists: Get medical advice/attention.*
P370+P378 *In case of fire: Use for extinction: CO2, powder or water spray.*
P403+P233 *Store in a well-ventilated place. Keep container tightly closed.*
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.*
- **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.*

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· Dangerous components:		
CAS: 64-17-5 EINECS: 200-578-6	Ethyl Alcohol ⚠ Flam. Liq. 2, H225	>50-≤100%
CAS: 868-77-9 EINECS: 212-782-2	2-Hydroxyethyl Methacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	>2.5-≤10%
	MDP ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	>2.5-≤10%

· **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:**

Take proper precautions to ensure your own health and safety before attempting rescue and providing first aid. Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area. Immediately remove any clothing soiled by the product.

· **After inhalation:**

Seek medical treatment in case of complaints.
Give oxygen or artificial respiration as needed.
In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:**

If skin irritation continues, consult a doctor.
Launder clothing before reuse.
Immediately wash with water and soap and rinse thoroughly.

· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:**

Do NOT induce vomiting.
If vomiting does occur, have victim lean forward to prevent aspiration.
Rinse mouth with water.
Seek medical treatment.
Never give anything by mouth to an unconscious person.

· **Information for doctor:**

· **Most important symptoms and effects, both acute and delayed**

Symptoms vary with alcohol level of the blood. Mild alcohol intoxication occurs at blood levels between 0.05-0.15%. Approximately 25% of individuals show signs of intoxication at these levels. Above 0.15% the person is definitely under the influence of ethanol; 50-95% of individuals are clinically intoxicated at these levels. Severe poisoning occurs when the blood is ethanol level is 0.3- 0.5%. Above 0.5% the individual will be comatose and death can occur. The unabsorbed ethanol should be removed by gastric lavage after intubating the patient to prevent aspiration. Avoid the use of depressant drugs or the excessive administration of fluids.

· **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

5 Firefighting measures

· **Extinguishing media**

· **Suitable extinguishing agents:**

Water fog
Alcohol resistant foam
Water spray
Carbon dioxide

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Dry Chemical

- **Special hazards arising from the substance or mixture**

*Carbon monoxide (CO)**May produce a floating fire hazard.**Static ignition hazard can result from handling and use.**Vapors may travel to source of ignition and flash back.**Vapors may settle in low or confined spaces.**Alcohols burn with a pale blue flame which may be extremely hard to see under normal lighting conditions.**Personnel may only be able to feel the heat of the fire without seeing flames. Extreme caution must be exercised in fighting alcohol fires. Fight fire from maximum distance or use unmanned hose holders or monitor nozzles. Cool containers with flooding quantities of water until well after fire is out. Withdraw immediately in case of rising sound from venting safety devices or discoloration of tank. Always stay away from tanks engulfed in fire.*

- **Advice for firefighters:**

- **Protective equipment:**

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

- **Additional information** *Cool endangered receptacles with water spray.*

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**

*Do not inhale vapors, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapors accumulating to form explosive concentrations. Vapors can accumulate in low areas.**Wear protective equipment. Keep unprotected persons away.*

- **Environmental precautions:**

*Stop leak. Contain spill if possible and safe to do so.**Do not allow to enter sewers/ surface or ground water.*

- **Methods and material for containment and cleaning up:**

*Highly flammable liquid. Eliminate all sources of ignition. All equipment used when handling this product must be grounded. A vapor suppressing foam may be used to reduce vapors. Do not touch or walk through spilled material. Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations. Use clean non-sparking tools to collect absorbed material.**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 contact with eyes, skin, and clothing.**Do not inhale vapor or mist.**Open and handle container with care.**Ensure good ventilation/exhaustion at the workplace.**Prevent formation of aerosols.*

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- **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:**
Metal containers involved in the transfer of this material should be grounded and bonded.
Store in a cool location.
- **Information about storage in one common storage facility:** Store away from flammable substances.
- **Further information about storage conditions:**
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Consult local fire codes for additional storage information.
See product labelling.
Keep container tightly sealed.
Store in cool, dry conditions in well - sealed receptacles.
- **Specific end use(s)** Professional Dental Bonding Agent

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.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Observe good industrial hygiene practices.
Ensure that washing facilities are available at the work place.
Electrical equipment should be grounded and confirm to applicable electrical code.
When using do not smoke.
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 and skin.
- **Respiratory protection:**
Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
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:**
Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product.
Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.
Wash and dry hands.

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**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:**

Maintain eye wash fountain and quick-drench facilities in work area.

Use equipment approved by appropriate government standards, such as NIOSH (US) or EN166 (EU)

Face protection

Use chemical safety goggles and/or a full face shield where splashing is possible.

**Tightly sealed goggles**

- **Body protection:**

Choose body protection according to the amount and concentration of the dangerous substance at the work place.

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:** 13 °C

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

- **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.

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· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not determined.
· Density at 20 °C:	0.8 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)	<99%
· 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:** Vapors may form explosive mixture with air.
- **Conditions to avoid:**
 - Direct sunlight
 - Extreme temperature
 - Sparks
 - Flames
 - Heat
- **Incompatible materials:**
 - Alkali metals
 - Strong Inorganic Acids
 - Peroxides
 - Oxidizing Agents
 - Ammonia
- **Hazardous decomposition products:** Carbon monoxide and carbon dioxide

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

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **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.
- **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)
868-77-9 2-Hydroxyethyl Methacrylate	
EC50	345 mg/l (Algae)

- **Persistence and degradability** Biodegradation is expected.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** Bioaccumulation is unlikely.
- **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.

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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**

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

14 Transport information

- | | |
|--|---|
| · UN-Number
· ADR, IMDG, IATA | UNI987 |
| · UN proper shipping name
· ADR
· IMDG, IATA | 1987 ALCOHOLS, N.O.S. (Ethyl Alcohol)
ALCOHOLS, N.O.S. (Ethyl Alcohol) |
| · Transport hazard class(es)
· ADR, IMDG, IATA | |
|  | |
| · Class
· Label | 3 Flammable liquids.
3 |
| · Packing group
· ADR, IMDG, IATA | II |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user
· Hazard identification number (Kemler code):
· EMS Number:
· Stowage Category | Warning: Flammable liquids.
33
F-E,S-D
B |
| · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · Transport/Additional information: | |
| · ADR
· Limited quantities (LQ)
· Excepted quantities (EQ) | 1L
Code: E2
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 500 ml |
| · Transport category
· Tunnel restriction code | 2
D/E |

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· IMDG	
· Limited quantities (LQ)	IL
· 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 1987 ALCOHOLS, N.O.S. (ETHYL ALCOHOL), 3, II

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
- **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.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
- **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
Flam. Liq. 2: Flammable liquids – Category 2
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
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3