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GB

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

Revision: 06.10.2022 Version number 1 Printing date 06.10.2022 l Identification of the substance/mixture and of the company/undertaking · Product identifier · Trade name: PO1TM · Article number: SDS 26-001.13, 63311 · 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 USAonlineordersupport@ultradent.com EC Responsible Person Ultradent Products GmbH Am Westhover 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 flame Flam. Liq. 3 H226 Flammable liquid and vapour. corrosion Skin Corr. 1A H314 Causes severe skin burns and eye damage. H318 Causes serious eye damage. Eye Dam. 1 Skin Sens. 1 H317 May cause an allergic skin reaction. STOT SE 3 H335 May cause respiratory irritation. (Contd. on page 2)

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	ing to Regulation (EC) No 1272/2008 Void ns GHS02, GHS05, GHS07 ger
· Hazard-determin	ing components of labelling:
Trade Secret	
2-Hydroxyethyl N	•
Methacrylic Acid	
Organophosphine	
• Hazard statemen	
	liquid and vapour.
	ere skin burns and eye damage.
	an allergic skin reaction.
	respiratory irritation.
· Precautionary sto	
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+P35	53 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P35	<i>Remove contact lenses, if present and easy to do. Continue rinsing.</i>
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.

	Trade Secret	>10-<25%
	 Skin Corr. 1A, H314; Eye Dam. 1, H318	
CAS: 868-77-9	2-Hydroxyethyl Methacrylate	>10-<25%
EINECS: 212-782-2	𝔅 Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
CAS: 64-17-5	Ethyl Alcohol	>1-<10%
EINECS: 200-578-6	🚸 Flam. Liq. 2, H225	
CAS: 2530-85-0	Silane	>0.1-<10%
EINECS: 219-785-8	𝔅 Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 79-41-4	Methacrylic Acid	>1-<10%
EINECS: 201-204-4	 Acute Tox. 3, H331; ♦ Skin Corr. 1A, H314; Eye Dam. 1, H318; ♦ Acute Tox. 4, H302; Acute Tox. 4, H312 	
	Specific concentration limit: STOT SE 3; H335: $C \ge 1 \%$	(Contd. on pa

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	Organophosphine Oxide	<1%
ELINCS: 423-340-5	🚸 Skin Sens. 1A, H317; Aquatic Chronic 4, H413	
	Butylated Hydroxytoluene	≥0.025-<0.25%
EINECS: 204-881-4	Aquatic Acute 1, H400; Aquatic Chronic 1, H410; () 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:

Rinse mouth with water.

- 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: 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:
- Wear fully protective suit.

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.
- · Reference to other sections
- See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

7 Handling and storage

- **Precautions for safe handling:** Ensure good ventilation/exhaustion at the workplace. 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 Dental Bonding Agent

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/m³, 1000 ppm

79-41-4 Methacrylic Acid

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

128-37-0 Butylated Hydroxytoluene

WEL Long-term value: 10 mg/m³

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

• Exposure controls

• Appropriate engineering controls No further data; see item 7.

· Individual protection measures, such as personal protective equipment

• General protective and hygienic measures:

Ensure that washing facilities are available at the work place.

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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· 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 Acrvlic · Odour: · 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: 36 °C · Decomposition temperature: Not determined. Not applicable (non-aqueous) · pH · Viscosity: · Kinematic viscosity Not determined. · Dynamic: Not determined. · Solubility Not miscible or difficult to mix. · water: · Partition coefficient n-octanol/water (log value) Not determined. · Vapour pressure: Not determined. · Density and/or relative density · Density at 20 °C: 1.39 g/cm^{3} · Relative density Not determined. · Vapour density Not determined. (Contd. on page 6)

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Other information	
Appearance:	
Form:	Liquid
Important information on protection of hea	ulth and
environment, and on safety.	
Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product is not explosive. However, formation o explosive air/vapour mixtures are possible.
Change in condition	
Evaporation rate	Not determined.
Information with regard to physical hazard cla	ISSES
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 flammab	ble 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 Stable

- · Chemical stability Stable under recommended conditions.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions: No dangerous reactions known.
- Conditions to avoid:

Light

Sparks

Flames

Heat

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

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11 Toxicological information

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LD/LC50	values relevant for	r classification:	
ATE (Acu	te Toxicity Estima	tes)	
Oral	LD50	17,667 mg/kg	
Dermal	LD50	8,333 mg/kg (rabbit)	
Inhalative	LC50/4 h	118 mg/l	
868-77-9	2-Hydroxyethyl M	ethacrylate	
Oral	LD50	3,275 mg/kg (mouse)	
		>5,000 mg/kg (rat)	
	LC50 Fish	>100 mg/l (Fish)	
Dermal	LD50	>3,000 mg/kg (rabbit)	
	LC50(Daphnia m	agna) 24.1 mg/l (daphnia)	
64-17-5 E	thyl 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)	
		20,000 mg/l (rat)	
7 9- 41-4 M	lethacrylic 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)	
162881-20	6-7 Organophosph	ine 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)	
128-37-0	Butylated Hydroxy	toluene	
Oral	LD50	10,700 mg/kg (Guinea pig)	
		1,040 mg/kg (mouse)	
		890 mg/kg (rat)	
	LC50 Fish	5.3 mg/l (Fish)	
Dermal	LD50	>2,000 mg/kg (rat)	

· STOT-single exposure May cause respiratory irritation.

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· Information on other hazar		
• Endocrine disrupting prope		
128-37-0 Butylated Hydrox	vtoluene	List 1
2 Ecological information		
• Toxicity		
• Aquatic toxicity:		
868-77-9 2-Hydroxyethyl M	ethacrvlate	
EC50	345 mg/kg (Algae)	
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 in	nvertebrates)
162881-26-7 Organophospl		,
EC50 (static)	>1.175 mg/kg (daphnia) (Toxicity to aquatic	invertebrates)
Aqua toxicity	≥0.008 mg/l (daphnia) (Daphnia Magna Rep	
Toxicity to Aquatic Plants (s	tatic) >0.26 mg/l (Plant) (Toxicity to algae)	
128-37-0 Butylated Hydrox	vtoluene	
Aqua toxicity (static)	0.48 mg/l (daphnia) (Toxicity to aquatic inve	ertebrates)
Persistence and degradabili	ty No further relevant information available.	
· Bioaccumulative potential 1	o further relevant information available.	
• Mobility in soil No further r		
• <i>Results of PBT and vPvB as</i> • <i>PBT:</i> Not applicable.	sessment	
• vPvB: Not applicable.		
· Endocrine disrupting prope	rties For information on endocrine disrupting prop	perties see section 11.
• Other adverse effects		
 Additional ecological inform General notes: 	nauon:	
	an Regulation) (Self-assessment): slightly hazardoi	is for water
Do not allow undiluted prod	uct or large quantities of it to reach ground water,	
Must not reach sewage wate	r or drainage ditch undiluted or unneutralised.	
3 Disposal consideration	s	
• Waste treatment methods		
· Recommendation		
	er in accordance with international, federal, state, a	and local regulations.
· Uncleaned packaging:		

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UN number or ID number	
ADR, IMDG, IATA	UN1987
UN proper shipping name	
ADR	1987 ALCOHOLS, N.O.S. (METHACRYLIC ACID, STABILIZED
IMDG, IATA	Ethyl Alcohol) ALCOHOLS, N.O.S. (METHACRYLIC ACID, STABILIZED, Ethy
	Alcohol)
Transport hazard class(es)	
ADR, IMDG, IATA	
Class	3 Flammable liquids.
Label	3
Packing group	
ADR, IMDG, IATA	III
Environmental hazards:	Not applicable.
Special precautions for user	Warning: Flammable liquids.
Hazard identification number (Kemler code): EMS Number:	30 F-E,S-D
Stowage Category	<i>B</i>
Maritime transport in bulk according to IMO	
instruments	Not applicable.
Transport/Additional information:	
ADR	
Limited quantities (LQ)	SL
Excepted quantities (EQ)	Code: El Maximum nat quantity par inner packaging: 30 ml
	Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
Transport category	<i>3</i>
Tunnel restriction code	D/E
IMDG	
Limited quantities (LQ)	5L
Excepted quantities (EQ)	Code: El
	Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
UN "Model Regulation":	UN 1987 ALCOHOLS, N.O.S. (METHACRYLIC ACID
UIN MOUEI REGULAION :	STABILIZED, ETHYL ALCOHOL), 3, III

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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
- \cdot 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.

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.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H331 Toxic if inhaled.

H335 May cause respiratory irritation.

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: 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 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 Skin Sens. 1A: Skin sensitisation - Category 1A 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

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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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