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1 Identification

- Other means of identification
- · Trade name: PermaSealTM
- · Article number: SDS 85-001.09R01, 63010, 35208, 35210, 1013, 631, 631-1, 631-P3, S130
- $\cdot \textit{Relevant identified uses of the substance or \textit{mixture and uses advised against}}$

Professional dental composite sealer

- · Application of the substance / the mixture Professional dental composite sealer
- · 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

(800) 552-5512

Ultradent Australia Pty Ltd.

Level 22/2 Market Street

Sydney NSW 2000

Australia

Email: info.anz@ultradent.com Toll Free: 1-800-290929

1011 Free. 1-800-290929

· Emergency telephone number:

CHEMTREC (NORTH AMERICA) : +1 (800) 424-9300

· Further information obtainable from: Customer Service

(INTERNATIONAL): +(703) 527-3887

2 Hazard(s) Identification

· Classification of the substance or mixture



Skin sensitisation – Category 1 H317 May cause an allergic skin reaction.

- · Label elements
- · GHS label elements Void
- · Hazard pictograms GHS07
- · Signal word Warning
- · Hazard-determining components of labelling:

Triethylene Glycol Dimethacrylate (>20-<40 %)

Trade Secret (≥1-<10 %)

Hazard statements

H317 May cause an allergic skin reaction.

· 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.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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P280 Wear protective gloves.

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P362+P364 Take off contaminated clothing and wash it before reuse.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P321 Specific treatment (see on this label).

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

3 Composition and Information on Ingredients

- · Chemical characterisation: Mixtures
- · **Description:** Mixture of substances listed below with nonhazardous additions.

· Dangerou	· Dangerous components:		
	Triethylene Glycol Dimethacrylate	>20-<40%	
	♦ Skin sensitisation – Category 1, H317	-	
	Trade Secret	≥1-<10%	
	♠ Acute toxicity - oral – Category 4, H302; Acute toxicity - dermal – Category 4, H312; Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319; Skin sensitisation – Category 1, H317; Flammable liquids – Category 4, H227		
	Organophosphine Oxide	≥0.1-<1%	
	🕩 Skin sensitisation – Category 1, H317	-	

Additional information: For the wording of the listed hazard phrases refer to section 16.

4 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:

If skin irritation continues, consult a doctor.

Immediately wash with water and soap and rinse thoroughly.

- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: If symptoms persist consult 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

Suitable extinguishing agents:

Foam, dry chemical, carbon dioxide

Use fire extinguishing methods suitable to surrounding conditions.

- · Special hazards arising from the substance or mixture No further relevant information available.
- · Protective equipment:

Wear self-contained respiratory protective device.

Wear fully protective suit.

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6 Accidental Release Measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- · 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 section 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:

Keep away from heat and direct sunlight.

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

- · Information about fire and explosion protection: No special measures required.
- · Storage:
- Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

Protect from exposure to the light.

Store in a cool place.

See product labelling.

· Specific end use(s)

Professional Dental Composite Sealer

None

8 Exposure controls and personal protection

- · Appropriate engineering controls No further data; see section 7.
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · Additional information: The lists valid during the making were used as basis.
- · Personal protective equipment:
- · General protective and hygienic measures:

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

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.

· Protection of hands:



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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: Goggles recommended during refilling
- · Body protection: Protective work clothing

9 Physical and Chemical Properties

· General Information

· Appearance:

Form: Liquid
Colour: Yellow
Odour: Acrylic

· Odour threshold: Not determined.

· pH-value: Not applicable (non-aqueous)

Change in condition

Melting point/freezing point:
 Initial boiling point and boiling range: Undetermined.
 Flash point:
 Flammability
 Decomposition temperature:
 Undetermined.
 150 °C
 Not applicable.
 Not determined.

• Ignition temperature: Product is not selfigniting.

• Explosive properties: Product does not present an explosion hazard.

· Explosion limits:

Lower: Not determined.
Upper: Not determined.
Vapour pressure: Not determined.
Density: Not determined.
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.

· Other information

• Particle characteristics Not applicable.

· Physical state Fluid

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10 Stability and Reactivity

- · Reactivity No further relevant information available.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions: No dangerous reactions known.
- · Conditions to avoid:

Ignition sources

Flames

Direct Light

Heat

- · 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	59,615 mg/kg (rat)			
Dermal	LD50	76,923 mg/kg			
109-16-0 T	109-16-0 Triethylene Glycol Dimethacrylate				
Oral	LD50	>5,000 mg/kg (rat)			
	LC50 Fish	16.4 mg/l (Fish) (Toxicity to fish)			
Dermal	LD50	>2,000 mg/kg (mouse)			
Trade Seci	Trade Secret				
Oral	LD50	1,550 mg/kg (rat)			
	LC50 Fish	19 mg/l (Fish)			
Dermal	LD50	2,000 mg/kg (rabbit)			
Inhalative	LC50/4 h	96 mg/l (rat)			
Organoph	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)			
D	uitant offoot				

- · 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 May cause an allergic skin reaction.
- · 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.

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12 Ecological Information

· Toxicity

· Aquatic toxicity:				
109-16-0 Triethylene Glycol Dimethacrylate				
EC50	>100 mg/kg (Algae)			
Biodegradability	28 days (Aerobic) (Biodegradability testing)			
Aqua toxicity	32 mg/l (daphnia) (No Observed Effect Concentration)			
Trade Secret				
EC50	42 mg/kg (Algae)			
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 (stat.	ic) >0.26 mg/l (Plant) (Toxicity to algae)			

- · 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

Dispose of contents/container in accordance with international, federal, state, and local regulations.

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

UN-Number		
ADG, ADN, IMDG, IATA	not regulated	
UN proper shipping name		
ADG, ADN, IMDG, IATA	not regulated	
Transport hazard class(es)		
ADG, ADN, IMDG, IATA		
· Class	not regulated	

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· Packing group · ADG, IMDG, IATA	not regulated	
· Environmental hazards:	Not applicable.	
· Special precautions for user	Not Applicable	
· Transport in bulk according to Annex I and the IBC Code	I of Marpol Not applicable.	
· UN "Model Regulation":	not regulated	

15 Regulatory information

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

None of the ingredients is listed.			
· Australian Inventory of Industrial Chemicals			
109-16-0	Triethylene Glycol Dimethacrylate		
	Trade Secret		
10373-78-1	Camphorquinone		

Standard for the Uniform Scheduling of Medicines and Poisons

Organophosphine Oxide

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

None of the ingredients is listed.

· Australia: Priority Existing Chemicals

None of the ingredients is listed.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I 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 from Section 3

H227 Combustible liquid.

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

- · 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

EINECS: European Inventory of Existing Commercial Chemical Substances

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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

NIOSH: National Institute for Occupational Safety

Flammable liquids - Category 4: Flammable liquids - Category 4

Acute toxicity - oral - Category 4: Acute toxicity - Category 4
Skin corrosion/irritation - Category 2: Skin corrosion/irritation - Category 2
Eye damage/irritation - Category 2A: Serious eye damage/eye irritation - Category 2A
Skin sensitisation - Category 1: Skin sensitisation - Category 1

* Data compared to the previous version altered.

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