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1 Identification

· Other means of identification

- · Trade name: TranscendTM
- · Article number: SDS 441-001.04R01, 4726, 1006864, 1006865, 1006866, 1006867, 1006868, 1006869, 1006870
- *Relevant identified uses of the substance or mixture and uses advised against Professional Dental Composite* • *Application of the substance / the mixture Professional Dental Composite*
- · 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

 Further information obtainable from: Customer Service
Emergency telephone number: CHEMTREC (NORTH AMERICA) : +1 (800) 424-9300 (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:

Hydroxypropyl Methacrylate (≥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.
- P280 Wear protective gloves.
- P362+P364 Take off contaminated clothing and wash it before reuse.

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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.

· Dangerous components:

0	1	
	Hydroxypropyl Methacrylate	≥1-<10%
	Eye damage/irritation – Category 2A, H319; Skin sensitisation – Category 1, H317	
6606-59-3	HDDMA	≥0-<10%
	Skin corrosion/irritation – Category 2, H315; Specific target organ toxicity (single exposure) – Category 3, H335	
4 1 1 1 1 1 1 1 1		

• Additional information:

For the wording of the listed hazard phrases refer to section 16. Not applicable None

4 First Aid Measures

• General information: Immediately remove any clothing soiled by the product.

• After inhalation:

This product is a thick paste, therefore inhalation is extremely unlikely.

Seek medical treatment in case of complaints.

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.
- 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 Fire Fighting Measures

· Suitable extinguishing agents:

Water spray, fog, or mist, 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 fully protective suit.

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:

Dispose contaminated material as waste according to section 13.

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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: Ensure good ventilation/exhaustion at the workplace.

- Information about fire and explosion protection: No special measures required.
- · 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:* Protect from exposure to the light. See product labelling.
- · Specific end use(s) Professional Dental Composite

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:



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: Not required.

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· Body protection: Protective work clothing

9 Physical and Chemical Properti	es
General Information	
· Appearance:	
· Form:	Paste
· Colour:	Shade dependent
· 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.	: Undetermined.
Flash point:	Not applicable.
· Flammability	Not determined.
Decomposition temperature:	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 applicable.
Density at 20 °C:	2.04 g/cm^3
Relative density	Not determined.
Vapour density	Not applicable.
Evaporation rate	Not applicable.
Solubility in / Miscibility with	
· water:	Insoluble.
Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
· Dynamic:	Not applicable.
· Kinematic:	Not applicable.
· Other information	
• Particle characteristics	Not determined.
· Physical state	Solid

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:

Light

Heat

· Incompatible materials: No further relevant information available.

· Hazardous decomposition products: No dangerous decomposition products known.

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11 Toxicological Information

- · Information on toxicological effects
- Acute toxicity Based on available data, the classification criteria are not met.
- 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.

12 Ecological Information

· Toxicity

- Aquatic toxicity: No further relevant information available.
- · 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, IMDG, IATA	not regulated	
· UN proper shipping name		
· ADG, ADN, IMDG, IATA	not regulated	

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· Transport hazard class(es)		
· ADG, ADN, IMDG, IATA · Class	not regulated	
· Packing group · ADG, IMDG, IATA	not regulated	
· Environmental hazards:	Not applicable.	
· Special precautions for user	Not Applicable	
• Transport in bulk according to Annex II and the IBC Code	of Marpol Not applicable.	
· UN "Model Regulation":	not regulated	

15 Regulatory information

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

75-56-9 Me		
	Inventory of Industrial Chemicals	
65997-17-3	Inorganic Glass	
41637-38-1	EOBPADMA	
	Trade Secret	
27813-02-1	Hydroxypropyl Methacrylate	
6606-59-3	HDDMA	
79-41-4	Methacrylic Acid	
13463-67-7	Titanium Dioxide	
10287-53-3	Ethyl-4-Dimethylamino Benzoate	
	Organophosphine Oxide	
75-56-9	Methyloxirane	
10373-78-1	Camphorquinone	
51274-00-1	Yellow Iron Oxide	
	Proprietary	
	Chromium Iron Oxide	
	Proprietary	
	Proprietary	
1332-37-2	Red Iron Oxide	
Standard fo	r the Uniform Scheduling of Medicines and Poisons	
75-56-9 Me	thyloxirane	S7
Pre	oprietary	S4, S
Australia: H	Priority Existing Chemicals	!
None of the	ingredients is listed.	

· Named dangerous substances - ANNEX I None of the ingredients is listed.

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· 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

H315 Causes skin irritation.

- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory 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 ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety 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 Specific target organ toxicity (single exposure) – Category 3: Specific target organ toxicity (single exposure) – Category 3 * Data compared to the previous version altered. AU