

Printing date 05.03.2025 Version number 1 Revision: 05.03.2025

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

- · Product identifier
- · Trade name: TranscendTM
- · Article number: SDS 441-001.03R01, 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

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

Ultradent Products Inc.

505 W. Ultradent Drive (10200 S)

South Jordan, UT 84095-3942

USA

onlineordersupport@ultradent.com

- · 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

The product is not classified, according to the GB CLP regulation.

- · Label elements
- · Labelling according to Regulation (EC) No 1272/2008 Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void

3 Composition/information on ingredients

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

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|-------------------------|---|-------------------|
| · Dangerous components: | | |
| CAS: 27813-02-1 | Hydroxypropyl Methacrylate | ≥0-<10% |
| EINECS: 248-666-3 | ♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319 | |
| | Methcrylated Resin | ≥0-<10% |
| | ♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319 | |
| CAS: 6606-59-3 | HDDMA | ≥0-<10% |
| EINECS: 229-551-7 | Skin Irrit. 2, H315; STOT SE 3, H335 | |
| | Organophosphine Oxide | ≥0-<0.1% |
| | Skin Sens 1A, H317: Aquatic Chronic 4, H413 | |

· Additional information:

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

Not applicable

None

4 First aid measures

- Description of first aid measures
- · General information: No special measures required.
- · After inhalation:

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

Seek medical treatment in case of complaints.

- · After skin contact: Generally the product does not irritate the skin.
- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: If swallowed in large quantities seek medical attention.
- · 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

Use fire extinguishing methods suitable to surrounding conditions.

- · Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters:
- · 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: Pick up mechanically.
- · 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.

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7 Handling and storage

- · Precautions for safe handling: No special measures required.
- · Information about fire and explosion protection: No special measures required.
- · 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:

Protect from exposure to the light.

See product labelling.

· Specific end use(s) Professional Dental Composite

8 Exposure controls/personal protection

- · Control parameters
- · 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.
- · Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

- · Respiratory protection: Not required.
- · Hand protection

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.

- · Eve/face protection Not required.
- · Body protection: Protective work clothing

9 Physical and chemical properties

- Information on basic physical and chemical properties
- · General Information

· Physical state Solid

· Colour: Shade dependent

· Odour: Acrylic

· Odour threshold:

Not determined.

· Melting point/freezing point: Undetermined.

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Boiling point or initial boiling point and boiling range Undetermined.

· Flammability Not determined.

· Lower and upper explosion limit

Lower: Not determined.
 Upper: Not determined.
 Flash point: Not applicable.
 Decomposition temperature: Not determined.

· **pH** Not applicable (non-aqueous)

· Viscosity:

Kinematic viscosityDynamic:Not applicable.Not applicable.

·Solubility

· water: Insoluble.

• Partition coefficient n-octanol/water (log value) Not determined. • Vapour pressure: Not applicable.

· Density and/or relative density

Density at 20 °C:
 Relative density
 Vapour density
 Not determined.
 Not applicable.

· Other information

· Appearance:

· Form: Paste

Important information on protection of health and

environment, and on safety.

• **Ignition temperature:** Product is not selfigniting.

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

· Change in condition

• Evaporation rate Not applicable.

· Information with regard to physical hazard classes

· Explosives Void · Flammable gases Void · Aerosols Void · Oxidising gases Void · Gases under pressure Void · Flammable liquids Void · 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 flammable gases in contact with water Void

Substances and mixtures, which emit flammable 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 No further relevant information available.

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- · 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:

Light

Heat

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

11 Toxicological information

- · Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Based on available data, the classification criteria are not met.

| · LD/LC50 values relevant for classification: | | |
|---|--|--|
| ATE (Acute Toxicity Estimates) | | |

Dermal LD50 >302,500-≤1,586,996 mg/k (rabbit)

Organophosphine Oxide

| Oral | LD50 | >2,000 mg/kg (rat) |
|--------|-----------|--|
| | LC50 Fish | >2,000 mg/kg (rat) >0.09 mg/l (Fish) (Toxicity to fish) |
| Dermal | | >2,000 mg/kg (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.
- · 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.
- · Information on other hazards
- · Endocrine disrupting properties

None of the ingredients is listed.

12 Ecological information

- · Toxicity
- · Aquatic toxicity:

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 (static) >0.26 mg/l (Plant) (Toxicity to algae)

- · Persistence and degradability No further relevant information available.
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

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- Endocrine disrupting properties The product does not contain substances with endocrine disrupting properties.
- Other adverse effects
- 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.

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.

| 14 Trans | port in | format | tion |
|----------|---------|--------|------|
| | | | |

| · UN number or ID number · ADR, IMDG, IATA | not regulated | |
|--|-----------------|--|
| · UN proper shipping name · ADR, ADN, IMDG, IATA | not regulated | |
| · Transport hazard class(es) | | |
| · ADR, ADN, IMDG, IATA · Class | not regulated | |
| · Packing group · ADR, IMDG, IATA | not regulated | |
| · Environmental hazards: | Not applicable. | |
| · Special precautions for user | Not Applicable | |
| · Maritime transport in bulk according to IMO instruments Not applicable. | | |
| · UN "Model Regulation": | not regulated | |

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · NIOSH-Ca (National Institute for Occupational Safety and Health)

75-56-9 Methyloxirane

- · Poisons Act
- · Regulated explosives precursors

None of the ingredients is listed.

· Regulated poisons

None of the ingredients is listed.

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· Reportable explosives precursors

None of the ingredients is listed.

Reportable poisons

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

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

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

NIOSH: National Institute for Occupational Safety

ATE: Acute toxicity estimate values

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

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

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard - Category 4

* Data compared to the previous version altered.