

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

Printing date 24.04.2019

Revision: 18.04.2019

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

- **Product identifier**
- **Trade name:** *ExperTemp™ (All Shades)*
- **Article number:** 6340, 6341, 6342, 6343, 6344, 6347
- **Index number:** SDS 336-001.07
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Temporary Crown & Bridge Material
- **Application of the substance / the mixture** *Professional Dental Temporary Crown & Bridge Material*
- **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**



GHS08 health hazard

Repr. 2 H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.



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.

- **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.
- **Hazard pictograms** *GHS07, GHS08*

(Contd. on page 2)

Safety data sheet

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Printing date 24.04.2019

Revision: 18.04.2019

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(Contd. of page 1)

· **Signal word** Warning· **Hazard-determining components of labelling:**

Aliphatic Dimethacrylate

Hydroquinone Monomethyl Ether

Poly(Alkylene Glycol) Diacrylate

· **Hazard statements**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.

· **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/protective clothing/eye protection/face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308+P313 IF exposed or concerned: Get medical advice/attention.

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.· **Dangerous components:**

	Aliphatic Dimethacrylate	5-≤10%
	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	
	Poly(Alkylene Glycol) Diacrylate	.5-≤10%
	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
CAS: 150-76-5	Hydroquinone Monomethyl Ether	1-<5%
EINECS: 205-769-8	⚠ Repr. 2, H361; ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412	

· **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:** Provide fresh air. Seek medical attention if problems persist.· **After skin contact:** 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. Rinse mouth immediately and drink plenty of water. Medical treatment necessary.

(Contd. on page 3)

Safety data sheet

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Printing date 24.04.2019

Revision: 18.04.2019

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(Contd. of page 2)

- **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 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Water spray. Extinguishing powder. Sand. Foam. Carbon dioxide (CO₂).
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters:**
- **Protective equipment:** No special technical measures are necessary.
- **Additional information** Coordinate fire-fighting measures to the fire surroundings.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Provide adequate ventilation. Avoid contact with skin.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Take up mechanically. Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).
- **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:** Store cartridge at ambient temperatures.. Avoid heat sources and direct sunlight.
- **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:**
The usual precautions when handling chemicals have to be obtained.
When using do not eat or drink.
See product labelling.
Keep container tightly sealed.
- **Specific end use(s)** Professional Dental Temporary Crown & Bridge Material

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

(Contd. on page 4)

Safety data sheet

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Printing date 24.04.2019

Revision: 18.04.2019

Trade name: *ExperTemp™ (All Shades)*

(Contd. of page 3)

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

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:** The usual precautions when handling chemicals have to be obtained.

· **Respiratory protection:** Not required.

· **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**

Suitable material:

Butyl rubber., NR (Natural rubber (Caoutchouc), Natural latex), PVC (Polyvinyl chloride).

Unsuitable material;

NBR (Nitrile rubber).

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:**



Tightly sealed goggles

· **Body protection:** Protective clothing.

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form:	Paste
Colour:	Light beige
Odour:	Nearly odourless
Odour threshold:	Not determined.

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

· **Change in condition**

Melting point/freezing point:	Not determined
Initial boiling point and boiling range:	Not determined

· **Flash point:** >100 °C

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

(Contd. on page 5)

Safety data sheet
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Printing date 24.04.2019

Revision: 18.04.2019

Trade name: **ExperTemp™ (All Shades)**

(Contd. of page 4)

· Decomposition temperature:	Not determined.
· Auto-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 at 20 °C:	~1.4 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Practically insoluble
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic at 20 °C:	~9,000 mPas
Kinematic:	Not determined.
· Solvent content:	
VOC (EC)	0.00 %
Solids content:	<90.0 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **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:** None by intended use.
- **Incompatible materials:** Radical former. Reducing agents.
- **Hazardous decomposition products:** None by intended use.

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	>10,000-50,000 mg/kg (rat)
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150-76-5 Hydroquinone Monomethyl Ether

Oral	LD50	500 mg/kg (rat)
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- **Primary irritant effect:**
- **Skin corrosion/irritation**
Irritant effect on the skin

(Contd. on page 6)

Safety data sheet

according to 1907/2006/EC, Article 31

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Revision: 18.04.2019

Trade name: **ExperTemp™ (All Shades)**

(Contd. of page 5)

- *Causes skin irritation.*
- **Serious eye damage/irritation**
Irritant effect on the eye.
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**
No experimental indications of mutagenicity in-vitro exist.
No experimental indications of mutagenicity in-vivo exist.
- **Carcinogenicity** *Based on available data, the classification criteria are not met.*
- **Reproductive toxicity**
Suspected of damaging fertility. Suspected of damaging the unborn child.
- **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:**
Do not allow uncontrolled leakage into the environment.
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**
Advice on disposal
Can be burnt together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge. Carry out a burning of hazardous waste according to official regulations.
Waste disposal number of waste from residues/unused products
070799 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of fine chemicals and chemical products not otherwise specified; wastes not otherwise specified

Waste disposal number of used product
200301 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; other municipal wastes; mixed municipal waste

Waste disposal number of contaminated packaging

(Contd. on page 7)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 24.04.2019

Revision: 18.04.2019

Trade name: **ExperTemp™ (All Shades)**

(Contd. of page 6)

200301 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; other municipal wastes; mixed municipal waste

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue	
HP 4	Irritant - skin irritation and eye damage
HP 10	Toxic for reproduction

- **Uncleaned packaging:**

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

14 Transport information

- **UN-Number**

- **ADR, ADN, 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.

- **Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable.

- **UN "Model Regulation":**

not regulated

15 Regulatory information

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

- **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**

H302 Harmful if swallowed.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H361 Suspected of damaging fertility or the unborn child.

(Contd. on page 8)

Safety data sheet
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Trade name: ExperTemp™ (All Shades)

(Contd. of page 7)

H412 Harmful to aquatic life with long lasting effects.

· **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

Acute Tox. 4: Acute toxicity – Category 4

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

Repr. 2: Reproductive toxicity – Category 2

Repr. 2: Reproductive toxicity – Category 2

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

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

GB2