

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/12/2012

SDS No : 336-001.5

Date Revised : 03/19/2015

Revision No : 4

ExperTemp™ (All Shades)

SECTION 1 : Identification of the substance/preparation and of the company/undertaking

1.1. Product identifier

Product code : 6340, 6341, 6342, 6343, 6344, 6347
Product name : ExperTemp™ (All Shades)
Product description : Temporary Crown And Bridge Material.

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses : Professional Dental Temporary Crown & Bridge Material

1.3. Details of the supplier of the safety data sheet

Manufacturer

Ultradent Products, Inc.
 505 W. 10200 S.
 South Jordan, UT 84095

Distributor

Ultradent Products GmbH
 Am Westhover Berg 30
 51149 Cologne Germany
 Email: infoDE@ultradent.com
Emergency Phone : +49(0)2203-35-92-0

1.4. Emergency telephone number

CHEMTREC (NORTH AMERICA) : (800) 424 - 9300
(INTERNATIONAL) : +1(703) 527 - 3887

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 1999/45/EC

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Danger symbols : Xi

R phrases : R36/38, R43

Classification according to Regulation (EC) No 1272/2008 [CLP]

Health : Eye Irritation
 Skin Irritation
 Skin Sensitization

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : Xi



Irritant

R&S statement(s) : R36/38: Irritating to eyes and skin.
 R43: May cause sensitization by skin contact.

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ExperTemp™ (All Shades)**Classification according to Regulation (EC) No 1272/2008 [CLP]**

Hazard pictogram(s) :

Exclamation
mark

Signal Word

: WARNING

Hazard statement(s)

: H315: Causes skin irritation.
H317: May cause an allergic skin reaction.

Precautionary statement(s)

Prevention

: P280: Wear protective gloves/protective clothing/eye protection/face protection.

Response

: P305: IF IN EYES:
P351: Rinse cautiously with water for several minutes.
P313: Get medical advice/attention.
P302+P352: IF ON SKIN: Wash with plenty of soap and water.
P501: Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

Storage

: P273: Avoid release to the environment.

Disposal

: P501: Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

2.3. Other hazards

Immediate concerns

: No other adverse human effects.

SECTION 3: Composition / information on ingredients**3.1. Substances**

Not Applicable

3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Aliphatic Dimethacrylate	N/A	-	5 - 10	Xi; R36/37/38; R43	H315; H319; H317; H335
Poly(alkyleneglycol) diacrylate	N/A	-	5 - 10	Xi; R36/38; R43	H315; H317; H319

For full text of H-statements and R-phrases: see SECTION 16.

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SECTION 4: First aid measures

4.1. Description of first aid measures

- Following eyes** : Hold eyelids apart and flush eyes with plenty of water for at least 5 minutes. Get medical attention.
- Following skin** : Wash with soap and water.
- Following ingestion** : If swallowed in small quantity the product is harmless, otherwise consult a doctor.
- Following inhalation** : No specific treatment is necessary since this material is not likely to be hazardous by inhalation.

4.2. Most important symptoms and effects, both acute and delayed

- Eyes** : Irritating to eyes.
- Skin** : May cause skin irritation and sensitization.
- Ingestion** : May be harmful if swallowed in large quantities.
- Inhalation** : None expected for this product.

4.3. Indication of any immediate medical attention and special treatment needed

- Notes to physician** : Not Applicable

SECTION 5: Fire fighting measures

5.1. Extinguishing media

- Extinguishing media** : Please see Fire Fighting Equipment under Section 5.3.

5.2. Special hazards arising from the substance or mixture

- Hazardous combustion products** : None known.
- Explosion hazards** : Not Determined
- Fire explosion** : Not Determined
- Sensitive to static discharge** : Not Determined
- Sensitivity to impact** : Not Determined

5.3. Advice for firefighters

- Fire fighting procedures** : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.
- Fire fighting equipment** : Water spray. Extinguishing powder, sand, foam, Carbon Dioxide

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General procedures** : Refer to Section 8 for Personal Protective Equipment.

6.2. Environmental precautions

- Water spill** : Not Available

6.3. Methods and material for containment and cleaning up

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Small spill : Absorb liquid in sawdust, sand or inert absorbent. Wipe up and discard in a suitable container.

Large spill : Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).

6.4. Reference to other sections

Reference to other sections : Not Applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling : Keep away from heat sources and direct sunlight.

Storage : See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

Shelf life : See product labeling

7.3. Specific end use(s)

Specific end use(s) : Professional Dental Temporary Crown & Bridge Material

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Not Determined

8.2. Exposure controls

Eye/face protection : Wear eye protection

Skin protection : Wear suitable protective clothing and gloves.

Respiratory protection : Good general ventilation should be sufficient to control airborne levels.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Paste

Colour : Color dependent

Odour : Odorless or no characteristic odor

Flash point : > 100°C

Solubility in water : Insoluble

9.2. Other information

Percent volatile : Not Volatile

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Stable

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10.2. Chemical stability

Chemical stability : Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization : None

10.4. Conditions to avoid

Conditions to avoid : None

10.5. Incompatible materials

Incompatible materials : Radical former. Reducing agents.

10.6. Hazardous decomposition products

Hazardous decomposition products : None

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Notes : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute)

96-hour LC₅₀ : Not Determined

48-hour EC₅₀ : Not Determined

96-hour EC₅₀ : Not Determined

12.2. Persistence and degradability

Persistence and degradability : Not Determined

12.3. Bioaccumulative potential

Bioaccumulative potential : Not Determined

12.4. Mobility in soil

Mobility in soil : Not Determined

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Not Determined

12.6. Other adverse effects

Environmental data : Information not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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Disposal method : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

SECTION 14: Transport information

14.1. UN number

UN number : N/A

14.2. UN proper shipping name

UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification : N/A

14.4. Packing group

Packing group : N/A

14.5. Environmental hazards

Marine pollutant #1 : Not Dangerous Goods

14.6. Special precautions for user

ADR - road : Not Dangerous Goods

RID - rail : Not Dangerous Goods

IMDG - sea : Not Dangerous Goods

IATA - air : Not Dangerous Goods

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk : Not Dangerous Goods

SECTION 15: Regulatory information

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

RoHS : Please refer to Medical Devices Directive 93/42/EEC

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

Additional information : None of the ingredients are listed with: SARA Sect. 355 (extremely hazardous substances) or SARA Sect.313 (specific toxic chemical listings). Prop 65- Chemicals known to cause cancer. They are not listed in the Cancerogenity categories with the following agencies: EPA, IARC, NTP, TLV, NIOSH-Ca, OSHA-Ca.

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R36/37/38: Irritating to eyes, respiratory system and skin.
R36/38: Irritating to eyes and skin.
R43: May cause sensitization by skin contact.
H315: Causes skin irritation.
H317: May cause an allergic skin reaction.

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H319: Causes serious eye irritation.

H335: May cause respiratory irritation.

Prepared by

: Anu Kattoju

Revision summary

: This SDS replaces the 03/03/2015 SDS. Revised: **Section 1:**
Section 2: . **Section 4:** NOTES TO PHYSICIAN.

General statements

: N/A= Not Applicable

Manufacturer disclaimer

: FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.