according to Regulation (EC) No. 453/2010

Dental Use



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SECTION 1 : Identification of the sub	ostance/preparation and of the company/undertaking
1.1. Product identifier	
Product code	: DH/71106
Product name	: ClearTemp™ LC
Product description	: Temporary Veneer Cement
1.2. Relevant identified uses of the su	ubstance or mixture and uses advised against
Relevant identified uses	: Professional Temporary Veneer Cement
1.3. Details of the supplier of the safe	ety 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) :(80 (INTERNATIONAL) :+1(,
SECTION 2: Hazards identification	
2.1. Classification of the substance o	r mixture
Classification according to Regulatio	n(EC) No 1272/2008 [CLP]
	: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.
Health	: Skin Irritation, Category 2 Eye Irritation, Category 2
2.2. Label elements	
Classification according to Regulatio	n(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. H319: Causes serious eye irritation.
Precautionary statement(s)	
Prevention	: P280: Wear protective gloves/protective clothing/eye protection/face protection.

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Response	: P305: IF IN EYES: P351: Rinse cautiously with water for several minutes. P337+P313: If eye irritation persists: Get medical advice/attention. P302+P352: IF ON SKIN: Wash with plenty of soap and water.
Storage	: P404: Store in a closed container.
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 Regulation(EC) No 1272/2008 [CLP]
Bis-GMA	1565-94-2	216-367-7	< 30	H315; H319; H317
Triethylene Glycol Dimethacrylate	109-16-0	203-652-6	< 30	Not classified
Methacrylic Acid	79-41-4	201-204-4	< 5	Skin Irr.,Cat. 2; EYE DMG.,Cat. 1; STOT SE,Cat. 3; H318; H335

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

SECTION 4: First aid measures	
4.1. Description of first aid mea	sures
Following eyes	: Immediately flush eyes with plenty of water. Get medical attention, if irritation persists.
Following skin	: Wash with soap and water.
Following ingestion	: Do not ingest. If large amount is swallowed seek medical attention.
Following inhalation	: No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.
4.2. Most important symptoms a	ind effects, both acute and delayed
Eyes	: May cause eye irritation.
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

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SECTION 5: Fire fighting measures	
5.1. Extinguishing media	
Extinguishing media	: Foam, dry chemical, carbon dioxide (CO2).
5.2. Special hazards arising from the	substance or mixture
Hazardous combustion products	: None known.
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.
SECTION 6: Accidental release meas	ures
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 Applicable
6.3. Methods and material for contain	ment and cleaning up
Small Spill	: Wipe up with dry cloth.
Large Spill	: Collect in tightly closed containers.
6.4. Reference to other sections	
Reference to other sections	: Not Applicable
SECTION 7: Handling and storage	
7.1. Precautions for safe handling	
Handling	: Use suitable protective equipment.
Storage	: See product labeling.
7.2. Conditions for safe storage, inclu	iding any incompatibilities
Shelf life	: See product labeling
7.3. Specific end use(s)	
Specific end use(s)	: Professional Temporary Veneer Cement
SECTION 8: Exposure controls / pers	sonal 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 p	roperties

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9.1. Information on basic physical and	I chemical properties	
Physical state	: Viscous substance	
Colour	: Clear	
Odour	: Acrylic	
9.2. Other information		
Percent volatile	: Not Determined	
SECTION 10: Stability and reactivity		
10.1. Reactivity		
Reactivity	: Stable	
10.2. Chemical stability		
Chemical stability	: Stable when stored and handled under recommended conditions.	
10.3. Possibility of hazardous reaction	IS	
Hazardous polymerization	: None	
10.4. Conditions to avoid		
Conditions to avoid	: Heat, flames, ignition sources, direct light.	
10.5. Incompatible materials		
Incompatible materials	: None known.	
10.6. Hazardous decomposition produ	icts	
Hazardous decomposition products	: None known.	
SECTION 11: Toxicological information	on and a state of the state of	
11.1. Information on toxicological effe	cts	
Acute		
Notes	: Device is biocompatible when used as directed by dental professionals per ISO 10993-1.	
SECTION 12: Ecological information		
12.1. Toxicity		
Toxicity	: Not Determined	
Aquatic toxicity (acute)		
96-hour LC ₅₀	: Not Determined	
48-hour EC ₅₀	: Not Determined	
96-hour EC ₅₀	: Not Determined	
12.2. Persistence and degradability		
Persistence and degradability	: Not Determined	
12.3. Bioaccumulative potential		
Bioaccumulative potential	: Not Determined	

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12.4. Mobility in soil	
Mobility in soil	: Not Determined
12.5. Results of PBT and vPvB assessr	nent
Results of PBT and vPvB assessment	: Not Determined
12.6. Other adverse effects	
Environmental data	: Not Available
SECTION 13: Disposal considerations	
13.1. Waste treatment methods	
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	: N/A
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 Ar	nex 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	: This product is not considered dangerous for transportation.
SECTION 16: Other information	

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Relevant H-statements (number and full text)	 : EYE DMG., Cat. 1: Eye Damage, Category 1 STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Category 3 Skin Irr., Cat. 2: Skin Irritation, Category 2 H315: Causes skin irritation. H317: May cause an allergic skin reaction. H318: Causes serious eye damage. H319: Causes serious eye irritation. H335: May cause respiratory irritation.
Prepared by	: Anu Kattoju
Revision summary	: This SDS replaces the 01/06/2015 SDS. Revised: Section 1: Date- Revised. Section 15: COMMENTS.
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.