

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 03/02/2006

SDS No : 39-001.10

Date Revised : 04/30/2015

Revision No : 9

Ultra-Blend® Plus**SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier**

Product code : BN/41601, BQ/41618
Product name : Ultra-Blend® Plus
Product description : Light activated liner and pulp capping material

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

Relevant identified uses : Professional Dental Liner

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

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

Health : Eye Irritation
 Skin Irritation

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.


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

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Hazard pictogram(s)	:	 <p>Exclamation mark</p>
Signal Word	:	WARNING
Hazard statement(s)	:	H315: Causes skin irritation. H319: Causes serious eye irritation.
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. P332+P313: If skin irritation occurs: Get medical advice/attention.
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 : None

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

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Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Calcium Hydroxide	1305-62-0	215-137-3	5	C; R34	H318; H317; H412; H335; H314; H370; H290; H302; H312
Triethylene Glycol Dimethacrylate	109-16-0	203-652-6	< 5	Xi; R43	H317
Phosphoric Acid, Tricalcium Salt (2:3)	7758-87-4	231-840-8	< 15	Xi; R36/37/38; R22	H315; H319; H335

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

SECTION 4: First aid measures

4.1. Description of first aid measures

- Following eyes** : Flush eye with water for 15 minutes. Get medical attention.
- Following skin** : Wash with soap and water. Get medical attention if irritation develops or persists.
- 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. 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 and effects, both acute and delayed

- Eyes** : Causes eye irritation.
- Skin** : Causes skin irritation.
- Ingestion** : None expected for this product.
- 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

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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 : Foam, dry chemical, carbon dioxide (CO₂).

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 : Do not allow to enter sewers or drains that may lead to waterways.

6.3. Methods and material for containment and cleaning up

Small spill : Wipe up with cloth, soap and water.
Large spill : Absorb with inert, damp non-combustible material, then flush area with water.

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, including any incompatibilities

Shelf life : See product labeling

7.3. Specific end use(s)

Specific end use(s) : Professional Dental Liner

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Not Determined

8.2. Exposure controls

Eye/face protection : Wear eye protection

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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 : Viscous paste
Colour : White or beige
Odour : Odorless or no characteristic odor

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 reactions

Hazardous polymerization : None

10.4. Conditions to avoid

Conditions to avoid : Acidic conditions, light exposure

10.5. Incompatible materials

Incompatible materials : Strong acids, metals

10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

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

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Ultra-Blend® Plus**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** : No data 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 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**

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

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R22: Harmful if swallowed.
 R34: Causes burns.
 R36/37/38: Irritating to eyes, respiratory system and skin.
 R43: May cause sensitization by skin contact.
 H290: May be corrosive to metals.
 H302: Harmful if swallowed.
 H312: Harmful in contact with skin.
 H314: Causes severe skin burns and eye damage.
 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.
 H370: Causes damage to organs (or state all organs affected, if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard).
 H412: Harmful to aquatic life with long lasting effects.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 02/26/2015 SDS. Revised: **Section 1:** . **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 10:** HAZARDOUS POLYMERIZATION. **Section 14:** VESSEL (IMO/IMDG) - MARINE POLLUTANT #1. **Section 16:** GENERAL STATEMENTS.

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.