

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 03/02/2006

SDS No : 39-001.11

Date Revised : 07/07/2016

Revision No : 10

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

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

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 : Skin Sensitization, Category 1

2.2. Label elements**Classification according to Directive 1999/45/EC**

Hazard pictogram(s) : Xi



Irritant

R& 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)



Exclamation
mark

Signal Word

: WARNING

Hazard statement(s)

: 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.

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.
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.(EC1975L0442-20/11/2003)

2.3. Other hazards

Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

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]
Diurethane Dimethacrylate (DUDMA)	72869-86-4	276-957-5	< 60	Not classified	Skin Sens.,Cat. 1; H317
Barium Sulfate	7727-43-7	231-784-4	< 11	Xi; R 36/38	Not classified
Calcium Hydroxide	1305-62-0	215-137-3	≤ 5	C; R34	Skin Irr.,Cat. 2; EYE DMG.,Cat. 1; STOT SE,Cat. 3; H315; H318; 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 eyes with water. Get medical attention if irritation develops or persists.

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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.

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

Eyes	: Causes eye irritation.
Skin	: Causes skin sensitization.
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	: Causes skin sensitization.
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SECTION 5: Fire fighting measures

5.1. Extinguishing media

Extinguishing media	: Foam, dry chemical, carbon dioxide (CO2).
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5.2. Special hazards arising from the substance or mixture

Hazardous combustion products	: None known.
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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.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General procedures	: Refer to Section 8 for Personal Protective Equipment.
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6.2. Environmental precautions

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

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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 : Barium Sulfate CAS: 7727-43-7

Control Parameters	Exposure Limits
OSHA TWA	15 mg/m ³
NIOSH TWA	10 mg/m ³ 5 mg/m ³
ACGIH TWA	10 mg/m ³
AIHA WHEEL	None
NIOSH REL	TWA 10 mg/m ³ (total) 5mg/m ³ (resp)
OSHA PEL	TWA 15 mg/m ³ (total) TWA 5 mg/m ³ (resp)

Australia Control Parameters
10 mg/m ³ TWA

Calcium Hydroxide CAS: 1305-60-0

Control Parameters	Exposure Limits
OSHA TWA	15 mg/m ³
NIOSH TWA	= 5mg/m ³
ACGIH TWA	= 5mg/m ³
AIHA WHEEL	None

Canada

Alberta	= 5 mg/m ³ TWA
British Columbia	= 5 mg/m ³ TWA
Ontario	5 mg/m ³ TWA
Quebec	5 mg/m ³ TWAEV

Australia	5 mg/m ³ TWA
Mexico	= 5 mg/m ³ TWA

8.2. Exposure controls

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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 : 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

Dermal LD₅₀ : > 4200 mg/kg mouse/rabbit
Notes : ~90% of the mixture consists of components of unknown toxicity (dermal)
Oral LD₅₀ : > 2200 mg/kg rat/mouse
Notes : < 1% of the mixture consists of components of unknown toxicity(oral)
Inhalation LC₅₀ : Not able to calculate ATE mix (inhalation) due to lack of data on the components.
Notes : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

SECTION 12: Ecological information

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12.1. Toxicity

Aquatic toxicity (acute) : Do not allow to enter sewers or drains that may lead to waterways.

12.2. Persistence and degradability

Persistence and degradability : Not classified

12.3. Bioaccumulative potential

Bioaccumulative potential : Not classified

12.4. Mobility in soil

Mobility in soil : Not Available

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

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 : NAP

14.2. UN proper shipping name

UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification : NAP

14.4. Packing group

Packing group : NAP

14.5. Environmental hazards

Marine pollutant #1 : NAP

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

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SECTION 15: Regulatory information

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

General comments : Please refer to Medical Devices Directive 93/42/EEC.

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

Additional information : Titanium Dioxide has been classified as a group 2B(possible human carcinogen), per IARC monograph..
This product is not considered dangerous for transportation.

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R34: Causes burns.
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
Skin Sens., Cat. 1: Skin Sensitization, Category 1
H315: Causes skin irritation.
H317: May cause an allergic skin reaction.
H318: Causes serious eye damage.
H335: May cause respiratory irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 04/30/2015 SDS. Revised: **Section 1**: MSDS No. **Section 2**: EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 3**: Wt.%. **Section 4**: EYES, INHALATION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE - SKIN. **Section 5**: EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 8**: . **Section 11**: ACUTE (DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat)). **Section 12**: CHEMICAL FATE INFORMATION, DISTRIBUTION, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), SECTION 12: Ecological information. **Section 14**: ROAD AND RAIL (ADR/RID), VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 UN number, Packing group. **Section 15**: COMMENTS, GENERAL COMMENTS, RoHS. **Section 16**: GENERAL STATEMENTS.

General statements : NAP = Not Applicable
NE = Not Established
TLV = Threshold Limit Value
PEL = Permittable exposure limits
MAK = Maximum Workplace Concentration
STEL = Short-term exposure limit
STEV = Short-term exposure value
TWA = Time Weighted Average
PPE = Personal Protective Equipment

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: 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.