

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010
Dental Use



Date Issued : 02/27/2006
SDS No : 30-001.9
Date Revised : 12/07/2016
Revision No : 9

Ultradent® LC Block-Out Resin

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

1.1. Product identifier

Product code : BO/10318
Product name : Ultradent® LC Block-Out Resin
Product description : Light cure laboratory block out and model resin

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

Relevant identified uses : Dental laboratory resin

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

Phone +49 (0) 2203-35-92-0
(office hours 0900 - 17:00)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation(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 : Acute Toxicity (Inhalation), Category 2
Skin Sensitization, Category 1

2.2. Label elements

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

Hazard pictogram(s) :



Exclamation
mark

Signal Word : WARNING

Hazard statement(s) : H317: May cause an allergic skin reaction.
H335: May cause respiratory irritation.

Precautionary statement(s)

Prevention : P261: Avoid breathing vapours.
P280: Wear protective gloves/eye protection.

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Response : P302+P352: IF ON SKIN: Wash with plenty of water.
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
P362+P364: Take off contaminated clothing and wash it before reuse.

Disposal : P501: Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3. Other hazards

Results of PBT and vPvB assessment

PBT: Not Applicable
vPvB: Not Applicable

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] |
|---|------------|------------|----------|---|
| 7,7,9(or7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5. 12-diazahexadecane- 1,16-diyl bismethacrylate | 72869-86-4 | 2769575 | 50 - 100 | Skin Sens.,Cat. 1; H317 |
| 2,2'-ethylenedioxydiethyl dimethacrylate | 109-16-0 | 203-652-6 | 10 - 25 | Skin Sens.,Cat. 1B; H317 |

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

SECTION 4: First aid measures

4.1. Description of first aid measures

General information : If symptoms occur or in case of doubt consult a doctor.

After eye contact. : Keep eye lids open and rinse them with ample amounts of clean running water for at least 15 minutes.
In case of permanent aches and pains please go and see the doctor.

After skin contact : Remove contaminated clothing.
In case of permanent aches and pains please go and see the doctor.

After swallowing : Rinse out mouth and drink plenty of water. Instantly call for doctor.

After inhalation : Move person to fresh air.
In case of persistent symptoms consult doctor.

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

General information : No further relevant information available.

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

: No further relevant information available.

SECTION 5: Fire fighting measures

5.1. Extinguishing media

Extinguishing media : Extinguishing powder, foam or water jet. Fight larger fires with water jet or

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alcohol-resistant foam.

For safety reason unsuitable extinguishing agents Water with a full water jet.

5.2. Special hazards arising from the substance or mixture

- General hazard** : Formation of toxic gases is possible during heating or case of fire.
Hazardous combustion products : Nitrogen Oxides (NO_x), Carbon monoxide (CO)

5.3. Advice for firefighters

- Fire fighting equipment** : In case of fire wear breathing equipment being independent of ambient air and suit provided full protection against chemicals.
Additional information: Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General procedures** : Wear protective equipment. Keep unprotected persons away. Avoid contact with eyes, skin and clothes.

6.2. Environmental precautions

- Water spill** : Inform respective authorities in case product reaches water or sewage system.
Do not allow to enter drainage system, surface or ground water.

6.3. Methods and material for containment and cleaning up

- : Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders). Send for recovery or disposal in suitable containers. Complete cleaning with water.

6.4. Reference to other sections

- 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 information on disposal.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- General procedures** : Keep containers tightly sealed.
Avoid direct contact with eyes, skin and clothing.
- Storage** : **Requirement to be met by storerooms and containers:**
Store only in the original container.
Keep container tightly closed and store upright to prevent any spill of product.
Information about storage in one common storage facility:
Keep away from food, drink and animal feeding stuffs.
Store away from oxidising agents.
Further information about storage conditions: Keep container tightly sealed.
Protect from direct sunlight.

7.2. Conditions for safe storage, including any incompatibilities

- Shelf life** : See product labeling

7.3. Specific end use(s)

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Specific end use(s) : No further relevant information available.

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : **Components with limit values that require monitoring at the workplace:**

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

Additional information: The lists that were valid during the compilation were used as basis.

8.2. Exposure controls

Eye/face protection : Tightly sealed safety glasses.

Skin protection : **Protective gloves.**
The glove material has to be impermeable and resistant to the product/the substance/the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks substances, the resistance of the glove material can not be calculated in advance and has therefore Butyl rubber, BR

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed. In case of a layer thickness of 0.7 mm the penetration time is longer than 480 minutes.

Body protection: Protective work clothing

Respiratory protection : Not necessary if room is well-ventilated.
Use breathing protection only when aerosol or mist is formed.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Gel
Appearance : Medium viscosity
Colour : Blue
Odour : Methacrylate
Odour threshold : NAP
pH : None (Not aqueous)
Melting temperature : < 25° C
Boiling temperature : > 100° C
Flash point : NAP
Evaporation rate : NAP
Flammability (solid, gas) : NAP

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| Flammable limits | : NAP |
| Vapor pressure | : NAP |
| Vapor density | : NAP |
| Specific gravity | : 1.1 to 1.2 |
| Solubility in water | : Insoluble |
| Partition coefficient: n-octanol/water | : NAP |
| Auto-ignition temperature | : NAP |
| Thermal decomposition | : 260 ° C (estimate from TGA trace) |
| Viscosity | : 46,000 cPs |

9.2. Other information

Additional information : No further relevant information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Polymerization under the influence of light.

10.2. Chemical stability

Chemical stability : Thermal decomposition/conditions to be avoided:
 No decomposition if used according to specifications.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions : No dangerous reactions known.

10.4. Conditions to avoid

Conditions to avoid : UV light

10.5. Incompatible materials

Incompatible materials : Strong oxidizing agents.

10.6. Hazardous decomposition products

Hazardous decomposition products : None known

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD₅₀ : > 2200 mg/kg Rabbit/Rat/Mouse

Notes : ~77% of the mixture consists of components of unknown toxicity (dermal)

Oral LD₅₀ : > 2300 mg/kg Rat

Notes : ~1% of the mixture consists of components of unknown toxicity (Oral).

Inhalation LC₅₀ : > 0.20 mg/L/4H Vapor Rat

Notes : ~92% of the mixture consists of components of unknown toxicity (inhalation).

Notes : Based on available data, the classification criteria are not met.

Skin corrosion/irritation : Based on available data, the classification criteria are not met.

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| Serious eye damage/irritation | : Based on available data, the classification criteria are not met |
| Respiratory or skin sensitisation | : May cause an allergic skin reaction. |
| Germ cell mutagenicity | : Based on available data, the classification criteria are not met |
| Carcinogenicity | : Based on available data, the classification criteria are not met |
| Reproductive toxicity | : Based on available data, the classification criteria are not met |
| 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 |
| Other information | : Device is biocompatible when used as directed by dental professionals per ISO 10993-1. |

SECTION 12: Ecological information

12.1. Toxicity

| | |
|---------------------------------|---|
| Toxicity | : General notes: 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 bodies or sewage system. |
| Aquatic toxicity (acute) | : No further relevant information available. |

12.2. Persistence and degradability

| | |
|--------------------------------------|---|
| Persistence and degradability | : No further relevant information available |
|--------------------------------------|---|

12.3. Bioaccumulative potential

| | |
|----------------------------------|---|
| Bioaccumulative potential | : No further relevant information available |
|----------------------------------|---|

12.4. Mobility in soil

| | |
|-------------------------|---|
| Mobility in soil | : No further relevant information available |
|-------------------------|---|

12.5. Results of PBT and vPvB assessment

| | |
|---|---|
| Results of PBT and vPvB assessment | : PBT : Not applicable vPvB : Not applicable |
|---|---|

12.6. Other adverse effects

| | |
|-------------------------|--|
| General comments | : No further relevant information available. |
|-------------------------|--|

SECTION 13: Disposal considerations

13.1. Waste treatment methods

| | |
|-------------------------|---|
| Product disposal | : Recommendation Must not be disposed of together with household garbage. Do not allow product to reach sewage system. The waste code numbers mentioned are recommendations based on the probable use of the product European waste catalogue |
|-------------------------|---|

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|----------------|--|
| 08 00 00 | WASTES FROM THE MANUFACTURE, FORMULATION, SUPPLY AND USE (MFSU) OF COATINGS(pAINTS, VARNISHES AND VITREOUS ENAMELS), ADHESIVES, SEALANTS AND PRINTING INKS |
| 08 04 00 | wastes from MFSU of adhesives and sealants (including waterproofing products) |
| 08 04 10 | waste adhesives and sealants other than those mentioned in 08 04 09 |

Uncleaned packagings

Recommendation: Dispose of packaging according to regulations on the disposal of packagings.

SECTION 14: Transport information**14.1. UN number**

UN number : Void

14.2. UN proper shipping name

UN proper shipping name : Void

14.3. Transport hazard class(es)

Hazard classification : Void

14.4. Packing group

Packing group : Void

14.5. Environmental hazards

Marine pollutant #1 : NAP

14.6. Special precautions for user

ADR - road : NAP

RID - rail : NAP

IMDG - sea : NAP

IATA - air : NAP

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

Transport in bulk : NAP

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****General information**

: Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Pictogram: GHS07

Signal word Warning

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Hazard-determining components of labelling:

7,7,9(or7 , 9,9)-trimethyl-4, 13-dioxo-3, 14-dioxo-5, 12-diazahexadecane-1, 16-diyl bismethacrylate 2,2'-ethylenedioxydiethyl dimethacrylate.

Hazard statements

H317 May cause all allergic skin reaction.

Precautionary statements

P261 Avoid breathing vapours.

P280 Wear protective gloves/ eye protection.

P302+P352 IF ON SKIN: Wash with plenty of water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P363 Take off contaminated clothing and wash it before reuse.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Directive 2012/18/EU

Named dangerous substances - ANNEX 1 None of the ingredients is listed. REGULATION (EC) No 1907/2006 ANNEX XV11 Conditions of restrictions: 3

National regulations

Information about limitation of use:

Employment restrictions concerning young persons must be observed.

Water hazard class: Water hazard class 1 (Self-assessment) : slightly hazardous for water.

| |
|--|
| Substances of very high concern (SVHC) according to REACH, Article 57 |
|--|

| |
|-----------------------------------|
| Contains none of the ingredients. |
|-----------------------------------|

15.2. Chemical safety assessment

Chemical safety assessment

: See Section 11

Additional information

: None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65.

This product is not considered dangerous for transportation.

SECTION 16: Other information

Relevant H-statements (number and full text)

: Skin Sens., Cat. 1B: Skin Sensitization, Category 1B
Skin Sens., Cat. 1: Skin Sensitization, Category 1
H317: May cause an allergic skin reaction.

Prepared by

: Anu Kattoju

Revision summary

: This SDS replaces the 03/24/2016 SDS. Revised: **Section 1:** Date-Revised. **Section 3:** Wt.%. **Section 14:** Packing group.

General statements

: NAP = Not Applicable
NE = Not Established

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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
AMU = Atomic Mass Unit

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.