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 EC Responsible Person

Ultradent Products, Inc.

505 W. 10200 S.

South Jordan, UT 84095

Ultradent Products GmbH
Am Westhover Berg 30
51149 Cologne Germany

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 dimethyacrylate	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

according to Regulation (EC) No. 453/2010

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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 (NOx), 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)

according to Regulation (EC) No. 453/2010

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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 goves does not only depend on the material, but also on further marks substances, the resistance of the glove material can not

be calcuated in advance and has therefore Butyl rubber, BR

Penetration time of glove material

The exact break though 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 threshhold : NAP

pH : None (Not aqueous)

Melting temperature $: < 25^{\circ}$  CBoiling temperature $: > 100^{\circ}$ CFlash point: NAPEvaporation rate: NAPFlammability (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 futher 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 dangeous 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 LD**<sub>50</sub> : > 2200 mg/kg Rabbit/Rat/Mouse

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

Oral LD<sub>50</sub> : > 2300 mg/kg Rat

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

Inhalation LC<sub>50</sub> : > 0.20 mg/L/4H Vapor Rat

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

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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### Ultradent® LC Block-Out Resin

08	WASTES FROM THE MANUFACTURE,
00	FORMULATION, SUPPLY AND USE (MFSU) OF
00	COATINGS(pAINTS, VARNISHES AND VITREOUS ENAMELS), ADHESIVES, SEALANTS AND PRINTING INKS
08 04 00	wastes from MFSU of adhesives and sealants (including water proofing 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

according to Regulation (EC) No. 453/2010

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# Hazard-determining components of labelling:

7,7,9(or7, 9,9)-trimethyl-4, 13-dioxo-3, 14-dioxa

-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 restictions: 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

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



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# Ultradent® LC Block-Out Resin

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.