

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/14/2006

SDS No : 84-001.8

Date Revised : 09/23/2015

Revision No : 7

Opalustre®**SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier**

Product code : OL/55403
Product name : Opalustre®
Product description : Chemical and mechanical abrasion slurry

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

Relevant identified uses : Professional Dental Abrasive Material

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 : R36/37/38

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

Health : Skin Corrosion, Category 1A
 Acute Toxicity (Inhalation), Category 3

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

Hazard pictogram(s) : Xi



Irritant

R&S statement(s) : R36/37/38: Irritating to eyes, respiratory system and skin.

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

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ULTRADENT
 PRODUCTS, INC.

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Hazard pictogram(s)	:	 <p>Exclamation mark</p>
Signal Word	:	DANGER
Hazard statement(s)	:	H331: Toxic if inhaled. H314: Causes severe skin burns and eye damage.
Precautionary statement(s)	:	
Prevention	:	P280: Wear protective gloves/protective clothing/eye protection/face protection.
Response	:	P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P313: Get medical advice/attention. P361: Take off immediately all contaminated clothing. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P315: Get immediate medical advice/attention. P301: IF SWALLOWED: P331: Do NOT induce vomiting. P311: Call a POISON CENTER or doctor/physician. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P304+P312: IF INHALED: Call a POISON CENTER or doctor/physician if you feel unwell.
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 : Harmful if inhaled.

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]
Hydrochloric Acid	7647-01-0	231-595-7	< 10	C; R34	Skin Corr.,Cat. 1A; Acute Tox. (I),Cat 3; H314; H331
Silicon Carbide	409-21-2	206-991-8	< 45	Xi; R37	Not classified

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** : Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Have eyes examined and tested by medical personnel.
- Following skin** : Remove contaminated clothing. Wash with soap and water. Get medical attention.
- Following ingestion** : If swallowed, Do Not Induce Vomiting- Seek Medical Advice.
- Following inhalation** : If inhaled, remove to fresh air. If breathing becomes difficult, call a physician.

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

- Eyes** : Causes eye irritation.
- Skin** : Causes skin irritation.
- Ingestion** : May be harmful if swallowed.
- Inhalation** : Harmful if inhaled

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

- Notes to physician** : Harmful if inhaled.

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

- Hazardous combustion products** : Hydrogen Chloride Gas

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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Opalustre®**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** : Pick up wash liquid with additional absorbent and place in a disposable container.**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, including any incompatibilities****Shelf life** : See product labeling**7.3. Specific end use(s)****Specific end use(s)** : Professional Dental Abrasive Material**SECTION 8: Exposure controls / personal 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** : Use only in well-ventilated areas.**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties****Appearance** : Gel**Colour** : Purple**Odour** : Acidic, DO NOT SMELL**9.2. Other information**

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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 : None known.

10.5. Incompatible materials

Incompatible materials : Oxidizing agents, organic materials, alkalis, water

10.6. Hazardous decomposition products

Hazardous decomposition products : Hydrogen Chloride Gas

SECTION 11: Toxicological information**11.1. Information on toxicological effects****Acute**

Notes : Device is an acid used for chemical abrasion, and is therefore toxic. It is to be used only as directed, and only by licensed dental professionals.

SECTION 12: Ecological information**12.1. Toxicity**

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

96-hour LC₅₀ : Not Determined48-hour EC₅₀ : Not Determined96-hour EC₅₀ : Not Determined**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 : Not Determined

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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 : 3264

14.2. UN proper shipping name

UN proper shipping name : Corrosive liquid, Acidic, Inorganic n.o.s. (Hydrochloric acid mixture)

14.3. Transport hazard class(es)

Primary hazard class/division : 8

Hazard classification : 8

14.4. Packing group

Packing group : II

14.5. Environmental hazards

Marine pollutant #1 : N/A

14.6. Special precautions for user

ADR - road : N/A

RID - rail : N/A

IMDG - sea : N/A

IATA - air : N/A

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

Transport in bulk : N/A

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

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full) : R34: Causes burns.
 R37: Irritating to respiratory system.

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text)	Acute Tox. (I), Cat 3: Acute Toxicity (Inhalation), Category 3 Skin Corr., Cat. 1A: Skin Corrosion, Category 1A H314: Causes severe skin burns and eye damage. H331: Toxic if inhaled.
Prepared by	: Anu Kattoju
Revision summary	: This SDS replaces the 04/10/2015 SDS. Revised: Section 1: . Section 2: EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. Section 4: INHALATION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE - INHALATION. Section 5: EXPLOSION HAZARDS, FIRE EXPLOSION, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT.
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.