

SAFETY DATA SHEET

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

ULTRADENT
PRODUCTS, INC.

Date Issued : 12/14/2006
SDS No : 84-001.9
Date Revised : 01/16/2017
Revision No : 8

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. Ultradent Drive (10200 South)
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 Regulation(EC) No 1272/2008 [CLP]

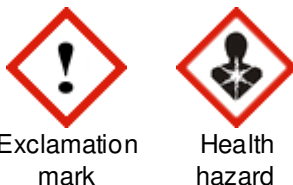
Health : Acute Toxicity (Oral), Category 4
Acute Toxicity (Inhalation), Category 3
Carcinogenicity, Category 1A
Eye Damage, Category 1

Physical : Metal Corrosion, Category 1

2.2. Label elements

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

Hazard pictogram(s) :



Signal Word : DANGER

Hazard statement(s) : H302: Harmful if swallowed.
H335: May cause respiratory irritation.
H350i: May cause cancer by inhalation.
H318: Causes serious eye damage.
H290: May be corrosive to metals.

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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. P315: Get immediate 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. P301: IF SWALLOWED: P330: Rinse mouth. P331: Do NOT induce vomiting. P312: Call a POISON CENTER or doctor/physician if you feel unwell. 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 1975L0442-21/11/2003)

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 Regulation(EC) No 1272/2008 [CLP]
Hydrochloric Acid	7647-01-0	231-595-7	< 10	EYE DMG.,Cat. 1; Met. Corr.,Cat. 1; H318; H290
Silicon Carbide	409-21-2	206-991-8	< 45	Carc.,Cat. 1A; H350i

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes	: Remove contact lenses, if present and easy to do. Flush eyes with plenty of water for at least 15 minutes, opening the eyelids fully. Seek immediate medical advice.
Following skin	: Wash with soap and water. Get medical attention if irritation develops or persists.
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.

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

Eyes : Can cause severe eye damage.
Skin : May cause skin irritation.
Ingestion : May be harmful if swallowed.
Inhalation : May be harmful if inhaled.

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

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.

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

General procedures : Avoid contact with eyes, skin and clothing.

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

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Opalustre®**SECTION 8: Exposure controls / personal protection****8.1. Control parameters**

Control parameters : Hydrochloric Acid CAS: 7647-01-0

Control Parameters	Exposure Limits
OSHA PEL General Industry	5 ppm (7mg/m ³)
OSHA PEL Construction Industry	5 ppm (7mg/m ³)
OSHA PEL Shipyard Industry	5 ppm (7mg/m ³)
NIOSH REL	5 ppm (7mg/m ³)
ACGIH TLV	2 ppm (2.98 mg/m ³)
CAL/OSHA PEL	5 ppm (7mg/m ³)

Silicon Carbide CAS: 409-21-2

Control Parameters	Exposure Limits
OSHA PEL General Industry	15 mg/m ³
OSHA PEL Maritime Industry	15 mg/m ³
NIOSH REL	10 mg/m ³ (total) TWA respirable

8.2. Exposure controls

Eye/face protection : Chemical splash goggles and face shield (ANSI 287.1 or equivalent) should be used by the doctor and patient.

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**

Physical state : Paste

Appearance : Uniform smooth

Colour : Purple

Odour : NAP

pH : < 1.0

9.2. Other information

Additional information : No further relevant information available.

SECTION 10: Stability and reactivity

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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

Dermal LD₅₀ : > 4000 mg/kg Mouse/Rabbit

Notes : ~44% of the mixture consists of components of unknown toxicity (Dermal).

Oral LD₅₀ : > 700 mg/kg Rat

Notes : ~44% of the mixture consists of components of unknown toxicity (oral)

Inhalation LC₅₀ : > 0.5 mg/L/4H Rat/Guinea Pig

Notes : ~44% of the mixture consists of components of unknown toxicity (Inhalation).

Carcinogenicity : WARNING! IARC has listed Silicon Carbide as a group 1A (possibly carcinogenic to humans).

Other information : 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.

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

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screening assessment; there are no indications of P or B properties.

12.6. Other adverse effects

Environmental data : No further relevant information 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 : 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 : Substances of very high concern (SVHC) according to REACH, Article 57: Contains no SVHC substances.

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

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

Additional information : WARNING! IARC has listed Silicon Carbide as a group 1A (probably carcinogenic to humans).

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SECTION 16: Other information

- Relevant H-statements (number and full text)** : Carc., Cat. 1A: Carcinogenicity, Category 1A
EYE DMG., Cat. 1: Eye Damage, Category 1
Met. Corr., Cat. 1: Metal Corrosion, Category 1
H290: May be corrosive to metals.
H318: Causes serious eye damage.
H350i: May cause cancer by inhalation.
- Prepared by** : Anu Kattoju
- Revision summary** : This SDS replaces the 09/23/2015 SDS. Revised: **Section 1:** MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 4:** EYES, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE (INHALATION, SKIN), SKIN. **Section 5:** EXTINGUISHING MEDIA, FIRE FIGHTING EQUIPMENT. **Section 7:** GENERAL PROCEDURES. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - EYES AND FACE . **Section 9:** APPEARANCE, COMMENTS, ODOR, PERCENT VOLATILE, pH, PHYSICAL STATE. **Section 11:** ACUTE (DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat) ACUTE, GENERAL COMMENTS, CARCINOGENICITY. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), SECTION 12: Ecological information. **Section 14:** VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, ADR - road, IMDG - sea, IATA - air. **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
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.