

# SAFETY DATA SHEET

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

**ULTRADENT**  
PRODUCTS, INC.

Date Issued : 12/13/2006  
SDS No : 81-001.7  
Date Revised : 05/18/2017  
Revision No : 6

## EtchArrest®

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

#### 1.1. Product identifier

Product code : EA/62515  
Product name : EtchArrest®  
Product description : Acid Barrier/Neutralizer

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

Relevant identified uses : Professional Dental Acid Barrier/Neutralizer

#### 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]

: 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 4

#### 2.2. Label elements

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

Hazard pictogram(s) :



Exclamation  
mark

**Signal Word** : WARNING

**Hazard statement(s)** : H332: Harmful if inhaled.

**Precautionary statement(s)**

**Prevention** : P261: Avoid breathing vapors.  
P271: Use only outdoors or in a well-ventilated area.

**Response** : P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.

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## EtchArrest®

P312: Call a POISON CENTER or doctor/physician if you feel unwell.

### 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]
Calcium carbonate	471-34-1	207-439-9	< 5	Skin Irr.,Cat. 2; Eye Irr.,Cat. 2A; H315; H319

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

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

**Following eyes** : Hold eyelids apart and flush eyes with plenty of water for at least 5 minutes. Get medical attention if irritation develops or persists.

**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** : Move person to fresh air; if effects occur, consult a physician.

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

**Eyes** : No specific hazards are encountered under normal product use.

**Skin** : No specific hazards are encountered under normal product use.

**Ingestion** : None expected for this product.

**Inhalation** : May be harmful if inhaled.

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

**Notes to physician** : NAP

## SECTION 5: Fire fighting measures

### 5.1. Extinguishing media

**Extinguishing media** : Water spray, fog, or mist, foam, dry chemical, carbon dioxide (CO<sub>2</sub>)

### 5.2. Special hazards arising from the substance or mixture

**Hazardous combustion products** : None known.

### 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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**EtchArrest®****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** : Wipe up small amounts with chemical resistant or damp rag which is washed with large amounts of water after each use. After cleaning, flush away traces with water.

**Large Spill** : After removal, flush contaminated area thoroughly with water.

**6.4. Reference to other sections**

**Reference to other sections** : NAP

**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 Acid Barrier/Neutralizer

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

**Control parameters** : Calcium Carbonate 471-34-1

Control Parameters	Exposure Limits
OSHA PEL General Industry	15 mg/m <sup>3</sup>
OSHA PEL Maritime Industry	15 mg/m <sup>3</sup>
ACGIH TLV	10 mg/m <sup>3</sup> TWA
NIOSH REL	10 mg/m <sup>3</sup> TWA

## International Regulations

Alberta	10 mg/m <sup>3</sup> TWA
Quebec	10 mg/m <sup>3</sup> TWAEV total dust
Australia	10 mg/m <sup>3</sup>

**8.2. Exposure controls**

**Eye/face protection** : Wear eye protection .

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**EtchArrest®**

**Skin protection** : Wear suitable gloves.  
**Respiratory protection** : Good general ventilation should be sufficient to control airborne levels. In case of insufficient ventilation, wear suitable respiratory equipment.

**SECTION 9: Physical and chemical properties**

**9.1. Information on basic physical and chemical properties**

**Physical state** : Viscous solution  
**Appearance** : Opaque  
**Colour** : Purple  
**Odour** : Odorless or no characteristic odor  
**pH** : 9.4  
**Specific gravity** : 1.16

**9.2. Other information**

**Additional information** : No further relevant information available

**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** : Acids and oxidizing agents

**10.5. Incompatible materials**

**Incompatible materials** : Not Determined

**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>** : > 44600 mg/kg Rabbit

**Notes** : < 10% of the mixture consists of components of unknown toxicity (Dermal).

**Oral LD<sub>50</sub>** : > 16800 mg/kg Rat/Guinea Pig

**Notes** : < 10% of the mixture consists of components of unknown toxicity (Oral).

**Inhalation LC<sub>50</sub>** : > 3.4 mg/l/4H Inhalation Category 4 Dust/Mist Rat

**Notes** : ~34% of the mixture consists of components of unknown toxicity (inhalation).  
 This substance is a viscous gel, therefore chance of inhalation is extremely low.

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**EtchArrest®**

<b>Germ cell mutagenicity</b>	: The components in this product are not reported to produce mutagenic effects in humans.
<b>Carcinogenicity</b>	: None of the components of this material are listed by IARC, NTP, or CA Prop 65 as carcinogens.
<b>Reproductive toxicity</b>	: The components in this product are not reported to cause reproductive effects in humans.
<b>Other information</b>	: Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

**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 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** : 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**

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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** : 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)** : Eye Irr., Cat. 2A: Eye Irritation, Category 2A  
Skin Irr., Cat. 2: Skin Irritation, Category 2  
H315: Causes skin irritation.  
H319: Causes serious eye 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 4:** INHALATION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE - INHALATION. **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** . **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY . **Section 9:** APPEARANCE, COMMENTS, PERCENT VOLATILE, pH, SPECIFIC GRAVITY. **Section 11:** ACUTE ( DERMAL LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat) ACUTE, GENERAL COMMENTS, CARCINOGENICITY, GERM CELL MUTAGENICITY, REPRODUCTIVE TOXICITY. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) ( 48-HOUR EC<sub>50</sub>, 96-HOUR EC<sub>50</sub> ), SECTION

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12: Ecological information. **Section 14:** ROAD AND RAIL (ADR/RID), VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, UN number, Packing group, 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

**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.