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

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]
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.
SAFETY DATA SHEET
according to Regulation (EC) No. 453/2010
Dental Use

EtchArrest®

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

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS</th>
<th>EINECS No.</th>
<th>Wt.%</th>
<th>Classification according to Regulation(EC) No 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>471-34-1</td>
<td>207-439-9</td>
<td>&lt; 5</td>
<td>Skin Irr., Cat. 2; Eye Irr., Cat. 2A; H315; H319</td>
</tr>
</tbody>
</table>

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 (CO₂)

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.
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

<table>
<thead>
<tr>
<th>Control Parameters</th>
<th>Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA PEL General Industry</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>OSHA PEL Maritime Industry</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>10 mg/m³ TWA</td>
</tr>
<tr>
<td>NIOSH REL</td>
<td>10 mg/m³ TWA</td>
</tr>
</tbody>
</table>

International Regulations

<table>
<thead>
<tr>
<th>Country</th>
<th>Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alberta</td>
<td>10 mg/m³ TWA</td>
</tr>
<tr>
<td>Quebec</td>
<td>10 mg/m³ TWAEV total dust</td>
</tr>
<tr>
<td>Australia</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>

8.2. Exposure controls
Eye/face protection: Wear eye protection.
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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Viscous solution</td>
</tr>
<tr>
<td>Appearance</td>
<td>Opaque</td>
</tr>
<tr>
<td>Colour</td>
<td>Purple</td>
</tr>
<tr>
<td>Odour</td>
<td>Odorless or no characteristic odor</td>
</tr>
<tr>
<td>pH</td>
<td>9.4</td>
</tr>
<tr>
<td>Specific gravity</td>
<td>1.16</td>
</tr>
</tbody>
</table>

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 LD₅₀ : > 44600 mg/kg Rabbit

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

Oral LD₅₀ : > 16800 mg/kg Rat/Guinea Pig

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

Inhalation LC₅₀ : > 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.
**Germ cell mutagenicity**: The components in this product are not reported to produce mutagenic effects in humans.

**Carcinogenicity**: None of the components of this material are listed by IARC, NTP, or CA Prop 65 as carcinogens.

**Reproductive toxicity**: The components in this product are not reported to cause reproductive effects in humans.

**Other information**: 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


### 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
SAFETY DATA SHEET
according to Regulation (EC) No. 453/2010
Dental Use

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

EtchArrest®

14.6. Special precautions for user

<table>
<thead>
<tr>
<th>ADR - road</th>
<th>NAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>RID - rail</td>
<td>NAP</td>
</tr>
<tr>
<td>IMDG - sea</td>
<td>NAP</td>
</tr>
<tr>
<td>IATA - air</td>
<td>NAP</td>
</tr>
</tbody>
</table>

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 LD₉₀ (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, GERM CELL MUTAGENICITY, REPRODUCTIVE TOXICITY. Section 12: CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀).
EtchArrest®

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.