Safety Data Sheet
PRÊMA®
Chemical and Mechanical Abrasion Slurry

1. Identification
   Product Name: PRÊMA®
   Product Description: Chemical and Mechanical Abrasion Slurry
   Premier® Dental Products Company
   1710 Romano Drive
   Plymouth Meeting, PA 19462 USA
   Phone: 610-239-6000  Fax: 610-239-6171
   Emergency Phone: 610-239-6000

   Recommended Use: Enamel Microabrasion
   Restrictions for Use: Patients with defects deep within the tooth structure such as tetracycline staining or dentinogenesis imperfect.

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 3
   - Acute Toxicity (Oral), Category 4
   - Eye Damage, Category 1
   - Carcinogenicity, Category 1A
   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):
   - H335: May cause respiratory irritation.
   - H302: Harmful if swallowed.
   - H318: Causes serious eye damage.
   - H350i: May cause cancer by inhalation.

   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:
   - 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.

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.

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 Directive 67/548/EEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>&lt; 10</td>
<td>EYE DMG.,Cat. 1; Met. Corr.,Cat. 1; H318; H290</td>
</tr>
<tr>
<td>Silicon Carbide</td>
<td>409-21-2</td>
<td>206-991-8</td>
<td>&lt; 45</td>
<td>Carc.,Cat. 1A; H350i</td>
</tr>
</tbody>
</table>

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

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.

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

5. Fire fighting measures
5.1. Extinguishing media
Extinguishing media: Foam, dry chemical, 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.

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

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

8. Exposure controls/personal protection
8.1. Control parameters
Control parameters: Hydrochloric Acid CAS: 7647-01-0

<table>
<thead>
<tr>
<th>Control Parameters</th>
<th>Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA PEL General Industry</td>
<td>5 ppm (7mg/m3)</td>
</tr>
<tr>
<td>OSHA PEL Construction Industry</td>
<td>5 ppm (7mg/m3)</td>
</tr>
<tr>
<td>OSHA PEL Shipyard Industry</td>
<td>5 ppm (7mg/m3)</td>
</tr>
<tr>
<td>NIOSH REL</td>
<td>5 ppm (7mg/m3)</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>2 ppm (2.98 mg/m3)</td>
</tr>
<tr>
<td>CAL/OSHA PEL</td>
<td>5 ppm (7mg/m3)</td>
</tr>
</tbody>
</table>

Silicon Carbide CAS: 409-21-2

<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>NIOSH REL</td>
<td>10 mg/m3 (total) TWA respirable</td>
</tr>
</tbody>
</table>

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.

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
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

11. Toxicological information

11.1. Information on toxicological effects
Acute
Der mal 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).
Car cinogenicity: 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.

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.

13. Disposal considerations
13.1. Waste treatment methods

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

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).

16. Other information
Premier’s revision date: 02/02/2017
Revision Number: 5

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.

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
Legal disclaimer

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