1. Identification

- **Product identifier**
  - Trade name: Bite Registration Material

- **Application of the substance or the preparation**
  - Addition curing vinyl polysiloxane dental impression materials (consisting of Base & Catalyst)

- **Manufacturer/Supplier**
  SmartPractice
  3400 E. McDowell Rd.
  Phoenix, AZ 85008, USA
  Tel: 1.800.522.8329
  Fax: 1.800.522.0800
  E-mail: info@smartpractice.com

- **24H Emergency Telephone number**
  Chemtrec: 1.800.424.9300

2. Hazards Identifications

The preparation of this document has been carried out according to the U.S. OSHA Hazard Communication Standard. Therefore, all the known hazards of the product or components has to be included regardless the potential risk.

- **Hazard classification**
  - Skin sensitizer: Category 1

- **Label elements**
  - Signal word: Warning.
  - Symbols: Exclamation mark.
  - Pictograms

- **Hazard statement**
  - May cause an allergic skin reaction.
  - Causes severe eye irritation.

- **Precautionary statements**
  - **Prevention:**
    - Wear protective gloves, protective clothing and eye protection.
    - Work clothing which is contaminated must not be allowed out of workplace.
    - Wash thoroughly after handling.

  - **Response:**
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IF ON SKIN: Wash with plenty of water and soap. In case skin irritation occurs, seek medical attention. Contaminated clothing must be washed before reuse.  
IF IN EYES: Rinse with caution with plenty of water for several minutes. In case contact lenses are worn remove and continue rinsing. If you feel unwell get medical attention.  
Disposal: Dispose of contents/container in accordance with applicable local/regional/national/international regulations.

- Classification system
  
  NFPA ratings (scale 0 – 4)
  Health = 2  
  Fire = 0  
  Reactivity = 0  

  HMIS ratings (scale 0 – 4)
  Health = *2
  Fire = 0
  Reactivity = 0

- Hazards not otherwise classified
  None.

3. Composition/Information on ingredients

- Chemical characterization
  Mixture of addition-curing silicones.

<table>
<thead>
<tr>
<th>C.A.S. No.</th>
<th>Component</th>
<th>% Wt</th>
</tr>
</thead>
<tbody>
<tr>
<td>68083-19-2</td>
<td>Polydimethylsiloxane vinyl terminated</td>
<td>20 – 40</td>
</tr>
<tr>
<td>68037-59-2</td>
<td>Dimethylsiloxane copolymer</td>
<td>1 – 10</td>
</tr>
<tr>
<td>14808-60-7</td>
<td>Quartz silica</td>
<td>30 – 50</td>
</tr>
<tr>
<td>27306-78-1</td>
<td>Polysiloxane</td>
<td>&lt; 5</td>
</tr>
</tbody>
</table>

4. First aid measures

Description of first aid measures

- After inhalation
  Remove person to fresh air. Get medical attention if you feel unwell.

- After contact with skin
  Immediately flush with water and then wash with soap and water. In case skin irritation persists, get medical attention.

- After contact with eyes
  Rinse with copious amounts of water for at least 15 minutes. Get medical attention.

- After ingestion
  Flush mouth with water and get medical attention.

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5. Fire-fighting measures

- **Suitable extinguishing media**
  Water spray, foam, carbon dioxide, dry chemicals depending on the materials involved in the fire.

- **Extinguishing media to avoid**
  Not known.

- **Special hazards arising from combustion**
  No relevant information is available for this product.

- **Special protective equipment for fire-fighters**
  No special measures are required.

6. Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
  Ventilate area. Avoid contact with skin and eyes.

- **Environmental precautions**
  Do not allow to enter sewers or ground water

- **Methods for cleaning up/collection**
  Collect mechanically. The product may be absorbed by liquid-binding material (sand, diatomite, acid binders).

7. Handling and storage

- **Precautions for safe handling**
  Adequately trained personnel should handle this product. Do not eat, drink or smoke when using the product. Wash thoroughly after handling. Contaminated clothing should not be allowed out of the workplace and in any case it should be washed before reuse. Keep container tightly closed.

- **Precautions in case of fire and explosion**
  Extinguish all sources of ignition. No special measures required.

- **Conditions for safe storage, including any incompatibilities**
  Store product in a cool and dry place. Avoid direct sunlight, strong bases, acids, oxidizing agents and amines. Store in the original container.

8. Exposure controls/personal protection

- **Control parameters**
  Occupational exposure limits

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In case a component is shown in section 3 but it does not appear in the table below, there are not any available data for this component.

<table>
<thead>
<tr>
<th>C.A.S. No.</th>
<th>Component</th>
<th>Agency</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>14808-60-7</td>
<td>Quartz silica</td>
<td>ACGIH</td>
<td>TWA: 0.025 mg/m³ respirable fraction</td>
</tr>
<tr>
<td>14808-60-7</td>
<td>Quartz silica</td>
<td>OSHA</td>
<td>TWA: 0.3 mg/m³ concentration as a total of dust</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TWA: 0.1 mg/m³ (2.4 millions of particles/cu. ft.) concentration respirable</td>
</tr>
</tbody>
</table>

ACGIH: American Conference of Government Industrial Hygienists
OSHA: United States Department of Labour – Occupational Safety and Health Administration
TWA: Time-Weighted Average

- Exposure control

Personal protective equipment (PPE)
Ventilation: Ensure adequate ventilation of the premises where the product is stored and/or handled.
Respiratory protection: Not required.
Hand protection: Suitable protective gloves may be worn. The use of vinyl gloves is suggested.
(Setting time of polyvinylsiloxanes is inhibited by latex gloves).
Eye protection: Safety goggles are recommended.
Skin protection: Do not eat, drink or smoke when using the product.
Other: Lab coat is suggested when using the product.

9. Physical and chemical properties

- Information on basic physical and chemical properties

Appearance: Bicomponent pastes/viscous liquids
Colour: Different
Odour: Characteristic
Odour threshold: Not available
pH value: Not applicable
Melting point: Not applicable
Boiling point: Not applicable
Flash point: Not applicable
Evaporation rate: No data available
Flammability (solid, gas): Not applicable
Density: 1,2-1,8 g/cm³
Vapour pressure: Not applicable
Vapour density: Not applicable
Viscosity: Not determined
Solubility: Insoluble in water
Auto ignition: Product is not self igniting
Flash point: No flash point
Boiling point: Not applicable
Viscosity: No data available

10. Stability and reactivity

- Reactivity

No relevant information available.
11. Toxicological information

It is required by the U.S. OSHA Hazard Communication Standard to include all the known hazards of the product or components included regardless the potential risk.
All the information presented below corresponds to the uncured components included in the product.
Once the product is mixed according to the instructions for use it is safe for its intended use.

- **Information on toxicological effects**
  - Inhalation: No adverse health effects are expected.
  - Skin contact: May cause mild irritation.
  - Eye contact: May cause irritation.
  - Ingestion: There is a possibility of gastrointestinal irritation with the symptoms being stomach pain and upset, nausea, diarrhoea and vomiting.

- **Additional toxicological information**
  - **Carcinogenicity:**
    - During normal / intended use it is not expected to cause the following health effect(s) during exposure

<table>
<thead>
<tr>
<th>C.A.S. No.</th>
<th>Component</th>
<th>Class description</th>
<th>Regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>14808-60-7</td>
<td>Quartz silica</td>
<td>Group 1: Carcinogenic to humans</td>
<td>International Agency for Research on Cancer</td>
</tr>
</tbody>
</table>

**Toxicological data:**
In case a component is shown in section 3 but it does not appear in the table below, there is not any available data for this component.

**Acute toxicity**

<table>
<thead>
<tr>
<th>Component</th>
<th>Route</th>
<th>Species</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polydimethylsiloxane vinyl terminated</td>
<td>Dermal</td>
<td>Rabbit</td>
<td>LD50 &gt; 15,440 mg/Kg</td>
</tr>
<tr>
<td></td>
<td>Ingestion</td>
<td>Rat</td>
<td>LD50 &gt; 15,440 mg/Kg</td>
</tr>
<tr>
<td>Dimethylsiloxane copolymer</td>
<td>Dermal</td>
<td>Rabbit</td>
<td>LD50 &gt; 2,000 mg/Kg</td>
</tr>
<tr>
<td></td>
<td>Ingestion</td>
<td>Rat</td>
<td>LD50 &gt; 2,000 mg/Kg</td>
</tr>
<tr>
<td></td>
<td>Inhalation</td>
<td>Rat</td>
<td>LC50 4.2 mg/l</td>
</tr>
<tr>
<td>Quartz silica</td>
<td>Dermal</td>
<td></td>
<td>LD50 &gt; 5,000 mg/Kg</td>
</tr>
<tr>
<td></td>
<td>Ingestion</td>
<td></td>
<td>LD50 &gt; 5,000 mg/Kg</td>
</tr>
<tr>
<td>Polysiloxane</td>
<td>Dermal</td>
<td>Rabbit</td>
<td>LD50 &gt; 2,000 mg/Kg</td>
</tr>
<tr>
<td></td>
<td>Ingestion</td>
<td>Rat</td>
<td>LD50 &gt; 2,000 mg/Kg</td>
</tr>
<tr>
<td></td>
<td>Inhalation</td>
<td>Rat</td>
<td>LC50 2 mg/l</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Skin corrosion/irritation</th>
<th>Species</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polydimethylsiloxane vinyl terminated</td>
<td>Rabbit</td>
<td>Mild irritation</td>
</tr>
<tr>
<td>Quartz silica</td>
<td></td>
<td>No significant irritation</td>
</tr>
<tr>
<td>Polysiloxane</td>
<td>Rabbit</td>
<td>No significant irritation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Serious eye damage/Irritation</th>
<th>Species</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polydimethylsiloxane vinyl terminated</td>
<td>Rabbit</td>
<td>Mild irritation</td>
</tr>
<tr>
<td>Polysiloxane</td>
<td>Rabbit</td>
<td>Severe irritation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Skin sensitization</th>
<th>Species</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polysiloxane</td>
<td>Guinea pig</td>
<td>Not sensitizing</td>
</tr>
</tbody>
</table>

Respiratory sensitization:
In case a component is shown in section 3 but it does not appear in the table below, there is not any available data for this component.

Germ cell mutagenicity

<table>
<thead>
<tr>
<th>Component</th>
<th>Route</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polysiloxane</td>
<td>In vitro</td>
<td>Not mutagenic</td>
</tr>
<tr>
<td>Quartz silica</td>
<td>In vitro</td>
<td>Not mutagenic</td>
</tr>
</tbody>
</table>

Carcinogenicity

<table>
<thead>
<tr>
<th>Component</th>
<th>Route</th>
<th>Species</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quartz silica</td>
<td>Inhalation</td>
<td>Human and Animal</td>
<td>Carcinogenic</td>
</tr>
</tbody>
</table>

Reproduced toxicity:
In case a component is shown in section 3 but it does not appear in the table below, there is not any available data for this component.

Reproduced and/or development effects

| Component | Route   | Value                                                                 | Species | Test Result     | Exposure duration |
|-----------|---------|                                                                      |---------|-----------------|-------------------|
| Polysiloxane | Ingestion | There is evidence for positive reproduction but limited data for classification | Rat     | NOAEL 450 mg/Kg/day | pre-mating & during gestation |

Target organ(s):
In case a component is shown in section 3 but it does not appear in the table below, there is not any available data for this component.

Specific target organ toxicity – single exposure
In case a component is shown in section 3 but it does not appear here, there is not any available data for this component.

Specific target organ toxicity – repeated exposure

<table>
<thead>
<tr>
<th>Component</th>
<th>Route</th>
<th>Target organ</th>
<th>Value</th>
<th>Species</th>
<th>Test Result</th>
<th>Exposure duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quartz silica</td>
<td>Inhalation</td>
<td>silicosis</td>
<td>Causes damage to organs through prolonged or repeated exposure</td>
<td>Human</td>
<td>NOAEL Not available</td>
<td>Occupational exposure</td>
</tr>
</tbody>
</table>
Aspiration hazard:
In case a component is shown in section 3 but it does not appear here, there is not any available data for this component.

12. Ecological information

If material is properly used and handled no ecological problems are to be anticipated
Do not discard material into drains/sewers or aquatic environment

13. Disposal considerations

Disposal must be carried out in accordance to the local and national regulations currently in force

14. Transport information

| UN-Number                                      | None |
| DOT, ADR, ADN, IMDG, IATA                    | None |
| UN proper shipping name                       | None |
| DOT, ADR, ADN, IMDG, IATA                    | None |
| Transport hazard class                        | None |
| DOT, ADR, ADN, IMDG, IATA                    | None |
| Class                                          | None |
| Packing Group                                  | None |
| DOT, ADR, IMDG, IATA                          | None |

15. Regulatory information

The product is not considered hazardous under D. Lgs. 65/03.
The product is a medical device according to EC directive 93/42/EEC
This product is classified as a medical device under US regulations and it has been reviewed by the US Food and Drug Administration (FDA)

16. Other information

CAUTION: PRODUCT FOR PROFESSIONAL USE ONLY
The information provided above is based on our present knowledge and experience. This safety data sheet refers explicitly to the product indicated and comprises no guarantee of particular quality. Any use of this product in any way not indicated on this safety data sheet will be exclusively under the user’s responsibility