1. Identification

- **Product identifier**
  Trade name: DEFEND Super Hydrophilic Vinyl Polysiloxane Impression Material (VPS), DEFEND Bite Registration Material, DEFEND CADbite, DEFEND ClearBite.

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

- **Manufacturer/Supplier**
  Mydent International
  80 Suffolk Court
  Hauppauge, NY 11788
  USA
  Tel: 631-434-3190
  800-275-0020
  Fax: 631-434-7750
  E-mail: sales@defend.com

- **24HR Emergency Telephone numbers**
  CHEMTREC (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.
DEFEND IMPRESSION MATERIAL/ PUTTY/ BITE REGISTRATION
SAFETY DATA SHEET

Issue Date: 05/25/2015 Version No: 1

Response:
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>
</tbody>
</table>
| 27306-78-1 | Polysiloxane                                | < 5

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.

Print date: 05/26/2015
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/collecting
  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
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>
</table>
| 14808-60-7 | Quartz silica| ACGIH     | TWA: 0.025* mg/m³  
*respirable fraction                                                   |
| 14808-60-7 | Quartz silica| OSHA      | TWA: 0.3 mg/m³  
*concentration as a total of dust  
TWA: 0.1 mg/m³ (2.4 millions of particles/cu. ft.)*concentration respirable |

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
10. Stability and reactivity

Reactivity
No relevant information available.

- Chemical stability
  Stable under normal storage and handle conditions.

- Hazardous decomposition products
  None, if used in accordance with instructions.

- Conditions to avoid
  No relevant information available, if used in accordance with instructions.

- Possibility of hazardous reactions
  None, if used in accordance with instructions

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>
</tbody>
</table>
**Ingestion**

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimethylsiloxane copolymer</td>
<td>Rabbit</td>
<td>LD50 &gt; 2,000 mg/Kg</td>
</tr>
<tr>
<td>Quartz silica</td>
<td>Rabbit</td>
<td>LD50 &gt; 2,000 mg/Kg</td>
</tr>
<tr>
<td>Polysiloxane</td>
<td>Rabbit</td>
<td>LD50 &gt; 2,000 mg/Kg</td>
</tr>
</tbody>
</table>

**Dermal**

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimethylsiloxane copolymer</td>
<td>Rabbit</td>
<td>LD50 &gt; 2,000 mg/Kg</td>
</tr>
<tr>
<td>Quartz silica</td>
<td>Rabbit</td>
<td>LD50 &gt; 2,000 mg/Kg</td>
</tr>
<tr>
<td>Polysiloxane</td>
<td>Rabbit</td>
<td>LD50 &gt; 2,000 mg/Kg</td>
</tr>
</tbody>
</table>

**Inhalation**

<table>
<thead>
<tr>
<th>Component</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>LC50 4.2 mg/l</td>
</tr>
</tbody>
</table>

**Skin corrosion/irritation**

<table>
<thead>
<tr>
<th>Component</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>No significant irritation</td>
<td></td>
</tr>
<tr>
<td>Polysiloxane</td>
<td>No significant irritation</td>
<td></td>
</tr>
</tbody>
</table>

**Serious eye damage/Irritation**

<table>
<thead>
<tr>
<th>Component</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>Severe irritation</td>
<td></td>
</tr>
</tbody>
</table>

**Skin sensitization**

<table>
<thead>
<tr>
<th>Component</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**

<table>
<thead>
<tr>
<th>Component</th>
<th>Route</th>
<th>Value</th>
<th>Species</th>
<th>Test Result</th>
<th>Exposure duration</th>
</tr>
</thead>
</table>
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>Occupation 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

<table>
<thead>
<tr>
<th>UN-Number</th>
<th>DOT, ADR, ADN, IMDG, IATA</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN proper shipping name</td>
<td>DOT, ADR, ADN, IMDG, IATA</td>
<td>None</td>
</tr>
<tr>
<td>Transport hazard class</td>
<td>DOT, ADR, ADN, IMDG, IATA</td>
<td>None</td>
</tr>
<tr>
<td>Class</td>
<td>DOT, ADR, IMDG, IATA</td>
<td>None</td>
</tr>
<tr>
<td>Packing group</td>
<td>DOT, ADR, IMDG, IATA</td>
<td>None</td>
</tr>
</tbody>
</table>
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