MIMIC IMPRESSION MATERIAL/ PUTTY/ BITE REGISTRATION SAFETY DATA SHEET

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

1. Identification

- **Product identifier**
  Trade name: Mimic Super Hydrophilic Vinyl Polysiloxane Impression Material (VPS), Mimic Bite Registration Material,

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

Manufacturer/Supplier

3D Dental Designs & Development

- 16781 Chagrin Blvd. Suite 434 Shaker Heights 44120

Tel: 877-605-8061
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- **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.

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.

C.A.S. No.	Component	% Wt
68083-19-2	Polydimethylsiloxane vinyl terminated	20 – 40
68037-59-2	Dimethylsiloxane copolymer	1 – 10
14808-60-7	Quartz silica	30 – 50
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.

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After ingestion
Flush mouth with water and get medical attention.

- **Further information** None

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.

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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.

C.A.S. No.	Component	Agency	Limit
14808-60-7	Quartz silica	ACGIH	TWA: 0.025* mg/m^3 * respirable fraction
14808-60-7	Quartz silica	OSHA	TWA: 0.3* mg/m^3 * concentration as a total of dust TWA: 0.1* mg/m^3 (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/cm^3
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

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Boiling point: Not applicable
Viscosity: No data available

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

C.A.S. No.	Component	Class description	Regulation
14808-60-7	Quartz silica	Group 1: Carcinogenic to humans	International Agency for Research on Cancer

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**

Component	Route	Species	Value
Polydimethylsiloxane vinyl terminated	Dermal	Rabbit	LD50 > 15,440 mg/Kg
	Ingestion	Rat	LD50 > 15,440 mg/Kg
Dimethylsiloxane copolymer	Dermal	Rabbit	LD50 > 2,000 mg/Kg
	Ingestion	Rat	LD50 > 2,000 mg/Kg
	Inhalation	Rat	LC50 4.2 mg/l
Quartz silica	Dermal		LD50 > 5,000 mg/Kg
	Ingestion		LD50 > 5,000 mg/Kg
Polysiloxane	Dermal	Rabbit	LD50 > 2,000 mg/Kg
	Ingestion	Rat	LD50 > 2,000 mg/Kg
	Inhalation	Rat	LC50 2 mg/l

Skin corrosion/irritation

Component	Species	Value
Polydimethylsiloxane vinyl terminated	Rabbit	Mild irritation
Quartz silica		No significant irritation
Polysiloxane	Rabbit	No significant irritation

Serious eye damage/Irritation

Component	Species	Value
Polydimethylsiloxane vinyl terminated	Rabbit	Mild irritation
Polysiloxane	Rabbit	Severe irritation

Skin sensitization

Component	Species	Value
Polysiloxane	Guinea pig	Not sensitizing

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

Component	Route	Value
Polysiloxane	In vitro	Not mutagenic
Quartz silica	In vitro	Not mutagenic

Carcinogenicity

Component	Route	Species	Value
Quartz silica	Inhalation	Human and Animal	Carcinogenic

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

Component	Route	Target organ	Value	Species	Test Result	Exposure duration
Quartz silica	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	Occupational exposure

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.

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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 **DOT, ADR, ADN, IMDG, IATA**	None
UN proper shipping name **DOT, ADR, ADN, IMDG, IATA**	None
Transport hazard class **DOT, ADR, ADN, IMDG, IATA** **Class**	None
Packing group **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 PROFESIONAL 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