

# SAFETY DATA SHEET

## according to OSHA HCS

Issue Date: 05/25/2015

Version No: 1

### 1. Identification

- **Product identifier**  
Trade name: iSmile Nano-Hybrid Posterior Light Curing Composite
- **Application of the substance or the preparation**  
Light curing dental filling material.
- **Manufactured For**  
iSmile Dental Products  
4201 Sierra Point Drive, Suite 102  
Sacramento, CA. 95834  
Tel: (888) 745-4737  
Fax: (888) 506-4002
- **24H Emergency Telephone numbers**  
ChemTel Contract No. MIS0007996  
North America: 1-800-255-3924  
International: +01-813-248-0585

### 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 have to be included regardless the potential risk.

- **Hazard classification**  
Serious eye damage/Irritation: Category 2B.  
Skin Sensitizer: Category 1B.
- **Label elements**  
Signal word: Warning.  
Symbols: Exclamation mark.  
Pictograms



**Restricted use by dental professional only.**

- **Hazard statement**  
Causes eye irritation.  
May cause an allergic skin reaction.
- **Precautionary statements**  
**Prevention:**  
Avoid breathing dust/mist/vapour/spray.  
Wear protective gloves and protective clothing.  
Wash thoroughly after handling.  
Keep in original container only.

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**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 eye irritation persists seek medical attention.

Disposal: Dispose of contents/container in accordance with applicable local/regional/national/international regulations.

- **Classification system**

NFPA ratings (scale 0 – 4)



Health = 1

Fire = 0

Reactivity = 0

HMIS ratings (scale 0 – 4)



Health = 1

Fire = 0

Reactivity = 0

- **Hazards not otherwise classified**

None

- **Other hazards**

Results of PBT and vPvB assessment.

PBT: not applicable

vPvB: not applicable

### 3. Composition/Information on ingredients

- **Chemical characterization**

Mixture of substances with methacrylate ester monomers.

| C.A.S. No. | Component                            | % Wt    |
|------------|--------------------------------------|---------|
| 109-16-0   | Dimethacrylate                       | 25 – 40 |
| 1565-94-2  | Dimetahcrylate                       | 20 – 35 |
| 41637-38-1 | Dimethacrylate                       | 25 – 40 |
| 7631-86-9  | Amorphous silica chemically prepared | 10 – 20 |
| 10287-53-3 | Parbenate                            | < 1     |
| 13463-67-7 | Titanium dioxide                     | < 1     |

### 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**

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Immediately flush with water and then wash with soap and water. In case skin irritation persists, get medical attention. Remove contaminated clothing and wash before reuse.

- **After contact with eyes**  
Rinse, opened eye, with copious amounts of water for at least 15 minutes. Remove contact lenses, if possible. Get medical attention.
- **After ingestion**  
Flush mouth with water. Get medical attention immediately.
- **Information for physician**  
**Most important symptoms and effects, both acute and delayed:** See Section 11.  
**Indication of any immediate medical attention and special treatment needed:** Not applicable.

### 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**  
None
- **Special hazards arising from combustion**  
No relevant information is available for this product.
- **Special protective equipment for fire-fighters**  
A self-contained breathing apparatus.

### 6. Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Ventilate area. Wear safety glasses, gloves and lab coat.
- **Environmental precautions**  
Avoid release to the environment. 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). Wash spill area with alcohol or water and soap.

### 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.
- **Conditions for safe storage, including any incompatibilities**  
Store product in a cool and dry place. Keep in original container with the cap always tightly closed. Protect from exposure to light, heat and direct sunlight.

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### 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.

| C.A.S. No. | Component        | Agency | Limit   |
|------------|------------------|--------|---|
| 13463-67-7 | Titanium dioxide | ACGIH  | TWA: 10 mg/m <sup>3</sup>                         |
| 13463-67-7 | Titanium dioxide | OSHA   | TWA: 15* mg/m <sup>3</sup><br>* as total dust     |
| 13463-67-7 | Titanium dioxide | CMRG   | TWA: 5* mg/m <sup>3</sup><br>* as respirable dust |

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 should be worn.

Eye protection: Safety glasses should be worn.

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:                | Liquid                              |
| Colour:                    | Off-white                           |
| Odour:                     | Characteristic                      |
| Odour threshold:           | Not available                       |
| pH value                   | Not available                       |
| Melting point:             | Not available                       |
| Boiling point:             | Not available                       |
| Flash point:               | Not available                       |
| Evaporation rate:          | No data available                   |
| Flammability (solid, gas): | Not applicable                      |
| Density:                   | Approximately 1,3 g/cm <sup>3</sup> |
| Vapour pressure:           | Not applicable                      |
| Vapour density:            | Not applicable                      |
| Viscosity:                 | Not determined                      |
| Solubility:                | Insoluble                           |
| Auto ignition:             | Product is not self igniting        |
| Boiling point:             | Not applicable                      |
| Viscosity:                 | No data available                   |

### 10. Stability and reactivity

- **Reactivity**

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The product is considered to be non reactive under normal use conditions.

- **Chemical stability**  
Stable under normal storage and handle conditions.
- **Hazardous decomposition products**  
None, if used in accordance with instructions.
- **Conditions and/or materials to avoid**  
Avoid storing the product at extreme temperatures (>27 °C and <5 °C) and direct sunlight. Avoid reducing and oxidizing agents, peroxides and amines.
- **Possibility of hazardous reactions**  
Hazardous polymerization will not occur.

### 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.**

**The risks of the hazards communicated in this document may vary depending on the potential of exposure.**

- **Information on toxicological effects**  
 Inhalation: Not expected to be an inhalation hazard despite the characteristic odour that it may have.  
 Skin contact: Mild Skin Irritation. Signs/symptoms may include localized redness, swelling, itching, and dryness. Allergic Skin Reaction. Signs/symptoms may include redness, swelling, blistering, and itching.  
 Eye contact: Moderate Eye Irritation. Signs/symptoms may include redness, swelling, pain, tearing, and blurred or hazy vision.  
 Ingestion: Gastrointestinal Irritation. Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhea.

- **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 | Regulation                                  |
|------------|--------------------------------------|-------|---|
| 7631-86-9  | Amorphous silica chemically prepared | 3     | International Agency for Research on Cancer |
| 13463-67-7 | Titanium dioxide                     | 2B    | 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, either there are not any available data for this component or the data are insufficient for classification.

**Acute toxicity**

| Component      | Route     | Species                | Value                              |
|----------------|-----------|------------------------|------------------------------------|
| Dimethacrylate | Dermal    | Professional judgement | LD50 estimated > 5,000 mg/Kg       |
|                | Ingestion | Rat                    | LD50 > 10,837 mg/Kg                |
| Dimethacrylate | Ingestion |                        | LD50 estimated 2,000 – 5,000 mg/Kg |

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|                  |                               |                        |                                    |
|------------------|-------------------------------|------------------------|------------------------------------|
|                  | Dermal                        | Professional judgement | LD50 estimated 2,000 – 5,000 mg/Kg |
| Dimethacrylate   | Dermal                        | Professional judgement | LD50 > 5,000 mg/Kg                 |
|                  | Ingestion                     | Rat                    | LD50 > 2,000 mg/Kg                 |
| Parbenate        | Dermal                        | Rat                    | LD50 > 2,000 mg/Kg                 |
|                  | Ingestion                     | Rat                    | LD50 > 2,000 mg/Kg                 |
| Titanium dioxide | Dermal                        | Rabbit                 | LD50 > 10,000 mg/Kg                |
|                  | Inhalation-Dust/Mist (4hours) | Rat                    | LD50 > 6.82 mg/l                   |
|                  | Ingestion                     | Rat                    | LD50 > 10,000 mg/Kg                |

**Skin corrosion/irritation**

| Component        | Species    | Value                      |
|------------------|------------|----------------------------|
| Dimethacrylate   | Guinea pig | Mild irritation            |
| Dimethacrylate   |            | Minimal irritation         |
| Parbenate        | Rabbit     | Not significant irritation |
| Titanium dioxide | Rabbit     | Not significant irritation |

**Serious eye damage/Irritation**

| Component        | Species               | Value                      |
|------------------|-----------------------|----------------------------|
| Dimethacrylate   | Professional judgment | Moderate irritation        |
| Dimethacrylate   |                       | Moderate irritation        |
| Parbenate        | Rabbit                | Mild irritation            |
| Titanium dioxide | Rabbit                | Not significant irritation |

**Skin sensitization**

| Component        | Species          | Value           |
|------------------|------------------|-----------------|
| Dimethacrylate   | Human and animal | Sensitizing     |
| Dimethacrylate   | Guinea pig       | Sensitizing     |
| Dimethacrylate   | Guinea pig       | Not sensitizing |
| Titanium dioxide | Human and animal | Not sensitizing |

**Respiratory sensitization:****Germ cell mutagenicity**

| Component        | Route    | Value  |
|------------------|----------|--|
| Dimethacrylate   | In vitro | Some positive data exist but there are insufficient for classification |
| Dimethacrylate   | In vitro | Some positive data exist but there are insufficient for classification |
| Dimethacrylate   | In vitro | Not mutagenic  |
| Titanium dioxide | In vitro | Not mutagenic  |
|                  | In vivo  | Not mutagenic  |

**Carcinogenicity**

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

| Component                            | Route  | Species | Value                                  |
|--------------------------------------|--------|---------|--|
| Dimethacrylate                       | Dermal | Mouse   | Not carcinogenic                       |
| Amorphous silica chemically prepared |        |         | Some positive data exist but there are |

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|---|------------|-------------------------|---------------------------------|
|   |            |                         | insufficient for classification |
| Titanium dioxide  | Ingestion  | Multiple animal species | Not carcinogenic                |
|   | Inhalation | Rat                     | Carcinogenic                    |

**Reproduced toxicity:**

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

**Reproduced and/or development effects**

| Component      | Route     | Value                            | Species | Test Result          | Exposure duration              |
|----------------|-----------|----------------------------------|---------|----------------------|--------------------------------|
| Dimethacrylate | Ingestion | Not toxic to female reproduction | Mouse   | NOAEL<br>1 mg/kg/d   | 1 generation                   |
| Dimethacrylate | Ingestion | Not toxic to male reproduction   | Mouse   | NOAEL<br>1 mg/kg/d   | 1 generation                   |
| Dimethacrylate | Ingestion | Not toxic to development         | Mouse   | NOAEL<br>1 mg/kg/d   | 1 generation                   |
| Dimethacrylate | Ingestion | Not toxic to female reproduction | Mouse   | NOAEL<br>0.8 mg/kg/d | prematuring & during gestation |
| Dimethacrylate | Ingestion | Not toxic to male reproduction   | Mouse   | NOAEL<br>0.8 mg/kg/d | prematuring & during gestation |
| Dimethacrylate | Ingestion | Not toxic to development         | Mouse   | NOAEL<br>0.8 mg/kg/d | prematuring & during gestation |

**Target organ(s):**

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

**Specific target organ toxicity – single exposure**

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

**Specific target organ toxicity – repeated exposure**

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

| Component      | Route     | Target organ(s)  | Value  | Species | Test Result          | Exposure duration              |
|----------------|-----------|--|--|---------|----------------------|--------------------------------|
| Dimethacrylate | Dermal    | Kidney and/or bladder  | Some positive data exist but there are insufficient for classification | Mouse   | NOAEL<br>833 mg/kg/d | 78 weeks                       |
| Dimethacrylate | Dermal    | Blood  | All data are negative  | Mouse   | NOAEL<br>833 mg/kg/d | 78 weeks                       |
| Dimethacrylate | Ingestion | Endocrine system, liver, nervous system, kidney and/or bladder | All data are negative  | Mouse   | NOAEL<br>0.8 mg/kg/d | prematuring & during gestation |

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**Aspiration hazard:**

In case a component is shown in section 3 but it does not appear here, there are 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 as it may cause pH variations.

### 13. Disposal considerations

Polymerize prior disposal. Disposal must be carried out in accordance to the local and national regulations currently in force.

### 14. Transport information

|   |      |
|---|------|
| <b>UN-Number</b><br>DOT, ADR, ADN, IMDG, IATA               | None |
| <b>UN proper shipping name</b><br>DOT, ADR, ADN, IMDG, IATA | None |
| <b>Transport hazard class</b><br>DOT, ADR, ADN, IMDG, IATA  | None |
| <b>Packing group</b><br>DOT, ADR, IMDG, IATA                | None |

### 15. Regulatory information

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.