

SAFETY DATA SHEET

according to OSHA HCS

Issue Date: 05/25/2015

Version No: 1

1. Identification

- **Product identifier**
Trade name: iSmile Flowable Composite – Micro-Hybrid
- **Application of the substance or the preparation**
Light curing dental filling material.
- **Manufacturer 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 ³
13463-67-7	Titanium dioxide	OSHA	TWA: 15* mg/m ³ * as total dust
13463-67-7	Titanium dioxide	CMRG	TWA: 5* mg/m ³ * 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 ³
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 1 mg/kg/d	1 generation
Dimethacrylate	Ingestion	Not toxic to male reproduction	Mouse	NOAEL 1 mg/kg/d	1 generation
Dimethacrylate	Ingestion	Not toxic to development	Mouse	NOAEL 1 mg/kg/d	1 generation
Dimethacrylate	Ingestion	Not toxic to female reproduction	Mouse	NOAEL 0.8 mg/kg/d	prematuring & during gestation
Dimethacrylate	Ingestion	Not toxic to male reproduction	Mouse	NOAEL 0.8 mg/kg/d	prematuring & during gestation
Dimethacrylate	Ingestion	Not toxic to development	Mouse	NOAEL 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 833 mg/kg/d	78 weeks
Dimethacrylate	Dermal	Blood	All data are negative	Mouse	NOAEL 833 mg/kg/d	78 weeks
Dimethacrylate	Ingestion	Endocrine system, liver, nervous system, kidney and/or bladder	All data are negative	Mouse	NOAEL 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

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	None
Packing group 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.