

SAFETY DATA SHEET

2/5/24

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: OpaFill Universal Composite Restorative
OpaFlow Flowable Composite Restorative

PRODUCT I.D.: All product numbers with prefixes:
OpaFill-, OpaFlow-

COMPANY: Opa Dental, LLC
105 Whitaker Blvd.
Huntington, WV 25701

PHONE: 1-304-523-6721

CHEMICAL NAME: BisGMA
CHEMICAL FORMULA: $C_{29}H_{36}O_8$

PRODUCT USE: Restorative

SECTION 2: COMPOSITION

Chemical Characterization: paste					
Composition:	Percentage:	CAS Number:	EC Number:	NFPA H/F/R/O*	HMIS H/F/PH/PP**
BisGMA $C_{29}H_{36}O_8$	15-30%	1565-94-2	N/A	N/A	N/A

Other substances	CAS#	Exposure Limit (mg/m3)
		OSHA PEL
UDMA	74389-53-0	N/A
TEGDMA	109-16-0	N/A
EBPADMA	41637-38-1	N/A
Photo-initiators	mixture	N/A
Silane treated barium glass	None	N/A
Silane treated zirconium-silicate	None	N/A
Silica (amorphous)	69012-64-2	N/A
Polymerization additives	Various	N/A

*Health, Flammability, Reactivity, Other information

**Health, Flammability, Physical Hazard, Personal Protection

SECTION 3: HAZARDS IDENTIFICATION

ROUTES OF ENTRY: Eyes, mouth, or skin.

POTENTIAL HEALTH EFFECTS

EYES: May irritate

SKIN: May irritate

INGESTION: May irritate

INHALATION: May irritate

CARCINOGENICITY: None known

SECTION 4: FIRST AID MEASURES

Potential Health Effects Primary Entry Routes: Inhalation (when the product is thermally degraded)

Target Organs: Upper respiratory tract.

Acute Effects/Chronic Effects: Solid product: Acute and chronic health effects are not expected as long as good industrial hygiene and safety precautions are followed.

Hot molten product: **Inhalation:** At elevated temperatures dense fumes may develop which can cause respiratory tract irritation and other breathing disorders. **Eye:** Contact with hot product will cause burns to the eyes.

Skin: Skin contact with hot material may result in severe burns.

Ingestion: No significant adverse effects are anticipated. If swallowed in large quantities, this material can obstruct the intestines.

Carcinogenicity: IARC, NTP, and OSHA do not list any components as carcinogens.

4. First Aid Measures

Inhalation: Remove to fresh air. If breathing is difficult, give oxygen and/or artificial respiration. **Eye**

Contact: Remove contact lenses. Hold eyelids apart. Immediately flush eyes with plenty of low-pressure water for at least 15 minutes. Get medical attention if irritation persists. HOT MOLTEN product: Cool burns with plenty of low-pressure water. Get immediate medical attention.

Skin Contact: Wash with soap and water. Get medical attention if irritation develops or persists. HOT MOLTEN product: Immediately cool skin with water and cold packs for at least 15 minutes. Do NOT put ice directly on the skin. Do NOT attempt to remove solidified wax from the skin as severe tissue damage may result. Get immediate medical attention. See Note to Physician.

Ingestion: Not an ingestion hazard under anticipated conditions of use. For accidental ingestion: If conscious, drink one to two glasses of water (8-16 oz.). Do not induce vomiting. Get immediate medical attention. Never give anything by mouth to an unconscious person.

Note to Physicians: For HOT MOLTEN or HOT LIQUID product: Material should not be forcibly pulled from the skin. Mineral oil may be used to loosen and soften the material.

SECTION 5: FIRE-FIGHTING MEASURES

EXTINGUISHING MEDIA: Normal extinguishing media

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: Standard measures, e.g. dust mask or dust collection device.

ACCIDENTAL RELEASE MEASURES: Avoid discharge into drains or surface water.

SECTION 7: HANDLING AND STORAGE

HANDLING: Only adequately trained personnel should handle this product. Keep out of reach of children. Usual hygienic measures are necessary. When using, do not eat, drink, or smoke. Provide adequate local ventilation or suction unit, especially in case of dust exposure.

STORAGE: No special requirements for place of storage and containers.

No further indications necessary for storage, no restrictions for storage with other products.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Provide adequate local ventilation.
Prepare material in proximity to an air suction unit.
Use a dust protection mask.
Avoid inhalation.
Safety eyewear necessary.

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

Appearance:	Plastic paste	Flexural strength:	70MPa
Aggregate State:	Solid/paste	Vickers hardness:	N/A
Odor:	N/A	Average grain size:	N/A
pH:	N/A	Radioactivity:	0Bq/g
Boiling Point:	200°C	Partition Coefficient:	N/A
Flash Point:	460°C	Solubility water/fat:	Insoluble in water
Auto-Flammability:	Not Self-Igniting	Chemical solubility:	Methyl ethyl ketone
Explosive Properties:	N/A	Viscosity:	N/A
Oxidizing Properties:	N/A	Vapor Density:	N/A
Vapor Pressure:	N/A	Evaporation Rate:	N/A
Relative Density:	1.18g/cm ³	Melting Point:	160°C

SECTION 10: STABILITY AND REACTIVITY

Conditions to avoid:	N/A
Materials to avoid:	N/A
Hazardous Decomposition products:	N/A

SECTION 11: TOXICOLOGICAL INFORMATION

Cytotoxicity	None
Short-term systemic toxicity	None
Sensitization (delayed hypersensitivity)	None
Cutaneous reactivity	None

SECTION 12: ECOLOGICAL INFORMATION

None

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Take to an approved landfill or waste incineration plant, under conditions approved by the local authorities.

SECTION 14: TRANSPORT INFORMATION

Not Hazardous

SECTION 15: REGULATORY INFORMATION

Class II medical device

Device #: 872.3690

Code: EBF

Required pre-market approval, regulated by the FDA, only distributed by FDA registered entities

ADDITIONAL INFORMATION

The Safety Data Sheet serves as a description of the products in regard to necessary safety measures. The indications do not guarantee properties.