

SAFETY DATA SHEET

11/05/2018

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: OpaFit™ impression material
OpaBite™ impression/bite material

PRODUCT I.D.: All product numbers with prefixes:
Opafit-, Opabite-

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

PHONE: 1-304-523-6721

CHEMICAL NAME: Poly dimethylsiloxane, vinyl terminated
CHEMICAL FORMULA: C₂H₆OSi

PRODUCT USE: Dental impression material

SECTION 2: COMPOSITION

Chemical Characterization: viscus vinyl compound					
Composition:	Percentage:	CAS Number:	EC Number:	NFPA H/F/R/O*	HMIS H/F/PH/PP**
Polyvinyl siloxane	<100%	68083-19-2	-	0/0/0/-	0/0/0/E

*Health, Flammability, Reactivity, Other information

**Health, Flammability, Physical Hazard, Personal Protection

SECTION 3: HAZARDS IDENTIFICATION

ROUTES OF ENTRY: vapor into 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

EYES: Wash eyes with large quantities of clean water for at least 15 minutes. In case of after-effects, call a physician.

SKIN: Wash thoroughly with warm water.

INGESTION: Rinse with water. In case of after-effects, call a physician.

INHALATION: Move person into fresh air.

SECTION 5: FIRE-FIGHTING MEASURES

EXTINGUISHING MEDIA: Normal extinguishing media

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: Standard measures, e.g. mask or vapor 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 protection mask.

Avoid inhalation of vapors.

Avoid vapor build-up.

Safety eyewear necessary.



SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Orange, blue, purple	Flexural strength:	N/A
Aggregate State:	Liquid to Solid	Vickers hardness:	N/A
Odor:	Odorless	Average grain size:	N/A
pH:	N/A	Radioactivity:	N/A
Boiling Point:	93°C	Partition Coefficient:	N/A
Flash Point:	113°C	Solubility water/fat:	Insoluble in water
Auto-Flammability:	Not Self-Igniting	Chemical solubility:	N/A
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:	0.965g/cm ³	Melting Point:	N/A

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
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SECTION 12: ECOLOGICAL INFORMATION

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 #: 872.3660

Code: ELW

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.