

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations Date Issued: 01 September 2007 Date Revised: 17 August 2015 Revision Number: 2

SECTION 1: Identification

1.1. Product identifier

Product form : Mixture

Product name : OptiFlow[™] Flowable Composite, OptiFlow[™] II Flowable Composite

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : For Professional Dental Use

1.3. Details of the supplier of the safety data sheet

Pac-Dent International Inc.

670 Endeavor Circle

Brea, CA 92821

1-909-839-0888

1.4. Emergency telephone number

Emergency number : CHEMTREC

800-424-9300 (USA)

001-703-527-3887 (Outside USA)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The product as manufactured is a solid composed of encapsulated chemical ingredients. No hazardous exposures are anticipated during normal product handling and use conditions.

GHS-US classification

Skin Irrit. 2 H315 Eye Irrit. 2A H319 Skin Sens. 1 H317 Repr. 1A H360

2.2. Label elements

GHS-US labelling

Hazard pictograms (GHS-US)





)7 G

Signal word (GHS-US) : Danger

Hazard statements (GHS-US) : H315 - Causes skin irritation

H317 - May cause an allergic skin reaction H319 - Causes serious eye irritation

Pacpent®
International, Inc.
passion for excellence...

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations Date Issued: 01 September 2007 Date Revised: 17 August 2015 Revision Number: 2

H360 - May damage fertility or the unborn child

Precautionary statements (GHS-US) : P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and

understood

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray

P264 - Wash ... thoroughly after handling

P272 - Contaminated work clothing should not be allowed out of the

workplace

P280 - Wear protective gloves/protective clothing/eye protection/face

protection

P302+P352 - IF ON SKIN: Wash with plenty of soap and water

P305+P351+P338 - If in eyes: Rinse cautiously with water for several

minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P308+P313 - IF exposed or concerned: Get medical advice/attention

P321 - Specific treatment (see ... on this label)

P332+P313 - If skin irritation occurs: Get medical advice/attention

 ${\tt P333+P313-If\,skin\,irritation\,or\,rash\,occurs:\,Get\,medical\,advice/attention}$

P337+P313 - If eye irritation persists: Get medical advice/attention

P362 - Take off contaminated clothing

P362+P364 - Take off contaminated clothing and wash it before reuse

P405 - Store locked up

P501 - Dispose of contents/container to ...

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

No data available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixture

Name	Product identifier	%	GHS-US classification
Chemical frits	(CAS No.) 65997-18-4	45-60	Repr. 1A, H360
			Aquatic Chronic 3, H412
2-Propenoic acid, 2-methyl-, (1-	(CAS No.) 1565-94-2	10 - 20	Skin Irrit. 2, H315
methylethylidene)bis[4,1-phenyleneoxy(2-			Eye Irrit. 2A, H319
hydroxy-3,1-propanediyl)] ester			Skin Sens. 1, H317
Polymerizable Dimethacrylate	Mixture	10-20	Skin Irrit. 2, H315
			Eye Irrit. 2A, H319
			Skin Sens. 1, H317
			STOT SE 3, H335
Silica, amorphous, fumed, crystalline-free	(CAS No.) 112945-52-5	1 - 10	Not classified

PacDent®
International, Inc.
passion for excellence...

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations Date Issued: 01 September 2007 Date Revised: 17 August 2015 Revision Number: 2

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : If medical advice is needed, have product container or label at hand.

First-aid measures after inhalation : Immediately seek fresh air. Open windows and/or doors to increase

ventilation. Seek medical attention if symptoms persist.

First-aid measures after skin contact : If irritation occurs and product is on the skin, rinse thoroughly with water,

followed by a thorough washing of the affected area with soap and water. If irritation, redness or swelling persists, contact a physician immediately.

First-aid measures after eye contact : Flush with copious amounts of water. Seek medical attention if symptoms

persist.

First-aid measures after ingestion : If ingested, do not induce vomiting. If product has been swallowed, drink

plenty of water or milk. If the patient is vomiting, continue to offer water or milk. Never give anything by mouth to an unconscious person. Provide an estimate of the time at which the material was ingested and the amount of the substance that was swallowed. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of

normal use.

4.3. Indication of any immediate medical attention and special treatment needed

If medical advice is needed, have product container or label at hand.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use Chemical Foam, CO2, Dry Chemical Powder, Water Spray. NOTE: Water

may be ineffective in extinguishing the fire.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Material may burn if exposed to flame.

Reactivity : Stable at ambient temperature and under normal conditions of use.

5.3. Advice for firefighters

Protection during firefighting : Firefighters should wear full protective gear.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

PacDent®
International, Inc.
passion for excellence...

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations Date Issued: 01 September 2007 Date Revised: 17 August 2015 Revision Number: 2

6.2. Environmental precautions

Keep spills and cleaning runoffs out of sewers and open bodies of water. Spills on porous surfaces can contaminate the ground water. Dispose of in accordance with Federal, State and Local regulations, or appropriate governing standards.

6.3. Methods and material for containment and cleaning up

For containment : If possible, stop flow of product.

Methods for cleaning up : Evacuate the spill area. Maximize ventilation by opening doors and

windows. Eliminate all sources of ignition. Use self-contained breathing apparatus and protective clothing, (e.g. goggles and gloves). Use non-sparking tools ONLY and dispose of the material in proper closed

container(s).

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : No special handling required.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep package closed and store in a cold dry place.

Incompatible materials : None known.

7.3. Specific end use(s)

For Professional Dental Use

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls : None required under normal product handling conditions.

Hand protection : Chemical resistant gloves should be worn when prolonged or repeated skin

contact is expected.

Eye protection : Safety glasses or chemical splash goggles may be worn, if necessary.

Skin and body protection : None required under normal product handling conditions.

Respiratory protection : A respirator should be worn whenever workplace conditions warrant its'

use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid Odour threshold : No data available
Appearance : Filled resin pH : No data available

Odour : Characteristic



Date Issued: 01 September 2007

Date Revised: 17 August 2015

Revision Number: 2

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Relative evaporation rate : No data available

(butylacetate=1)

Melting point : No data available Freezing point : No data available **Boiling point** : No data available Flash point : No data available Self ignition temperature : No data available Decomposition temperature : No data available : No data available Flammability (solid, gas) Vapour pressure : No data available Relative vapour density at 20 °C : No data available Specific gravity : 1.6 g/cc @ 25°C/77°F Solubility : No data available : No data available Log Pow : No data available Log Kow : No data available Viscosity, kinematic Viscosity, dynamic : No data available : No data available Explosive properties

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Oxidising properties

Explosive limits

Stable at ambient temperature and under normal conditions of use.

10.2. Chemical stability

Stable at standard temperature and pressure.

10.3. Possibility of hazardous reactions

May occur in large quantities.

10.4. Conditions to avoid

None

10.5. Incompatible materials

High temperatures, visible light sources, strong oxidizing agents. Keep away from sunlight and open flames.

: No data available

: No data available

10.6. Hazardous decomposition products

Oxides of carbon when burned.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified



according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations Date Issued: 01 September 2007 Date Revised: 17 August 2015 Revision Number: 2

Polymerizable Dimethacrylate	
LD50 oral rat	10837 mg/kg
ATE (oral)	10837 mg/kg

Chemical frits (65997-18-4)	
LD50 oral rat	> 2000 mg/kg

Silica, amorphous, fumed, crystalline-free (112945-52-5)	
LD50 oral rat	3160 mg/kg
ATE (oral)	3160 mg/kg

Skin corrosion/irritation : Causes skin irritation.

Serious eye damage/irritation : Causes serious eye irritation.

Respiratory or skin sensitisation : May cause an allergic skin reaction.

Germ cell mutagenicity : Not classified Carcinogenicity : Not classified

Silica, amorphous, fumed, crystalline-free (112945-52-5)	
IARC group	3

Reproductive toxicity : May damage fertility or the unborn child.

Specific target organ toxicity (single

exposure)

: Not classified

Specific target organ toxicity

(repeated exposure)

: Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of contents/container in accordance with

local/regional/national/international regulations.

PacDent®
International, Inc.
passion for excellence...

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations Date Issued: 01 September 2007 Date Revised: 17 August 2015 Revision Number: 2

SECTION 14: Transport information

In accordance with DOT / ADR / RID / ADNR / IMDG / ICAO / IATA

14.1. UN number

Not applicable

14.2. UN proper shipping name

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

Polymerizable Dimethacrylate	
Listed on the United States TSCA (Toxic Substances Control Act) inventory

2-Propenoic acid, 2-methyl-, (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] ester (1565-94-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Chemical frits (65997-18-4)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Silane, dichlorodimethyl-, reaction products with Silica (68611-44-9)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 4	Flammable liquids Category 4
Repr. 1A	Reproductive toxicity Category 1A
Skin Corr. 1B	skin corrosion/irritation Category 1B
Skin Irrit. 2	skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitisation Category 1
Skin Sens. 1B	Skin sensitisation Category 1B
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H302	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage

PacDent®
International, Inc.
passion for excellence...

according to Federal Register / Vol. 77, No. 58 / Monday,March 26, 2012 / Rules and Regulations Date Issued: 01 September 2007 Date Revised: 17 August 2015 Revision Number: 2

H319	Causes serious eye irritation
H335	May cause respiratory irritation
H360	May damage fertility or the unborn child
H412	Harmful to aquatic life with long lasting effects

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.