

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product form : Mixture
Product name : Quala 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

NDC, Inc.
402 BNA Drive, Suite 500
Nashville, TN 37217
Telephone: 800-929-4232

1.4. Emergency telephone number

Emergency number : 800-424-9300 CHEMTREC / Outside USA 001-703-527-3887

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) :



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
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

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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

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-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] ester	(CAS No.) 1565-94-2	10 - 20	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Skin Sens. 1, H317
Poly(oxy-1,2-ethanediyl), .alpha.,.alpha.'-[(1-methylethylidene)di-4,1-phenylene]bis[.omega.-[(2-methyl-1-oxo-2-propenyl)oxy]-	(CAS No.) 41637-38-1	10-20	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Skin Sens. 1, H317 STOT SE 3, H335
Silane, dichlorodimethyl-, reaction products with Silica	(CAS No.) 68611-44-9	1 - 10	Not classified
Silica, amorphous, fumed, crystalline-free	(CAS No.) 112945-52-5	1 - 10	Not classified
2-Propenoic acid, 2-methyl-, 1,6-hexanediyl ester	(CAS No.) 6606-59-3	1 - 10	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335
Triethylene glycol dimethacrylate	(CAS No.) 109-16-0	1 - 10	Not classified
Sodium fluoride	(CAS No.) 7681-49-4	1-5	Acute Tox. 3 (Oral), H301 Skin Irrit. 2, H315 Eye Irrit. 2A, H319

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

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.

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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
- Appearance : Filled resin
- Odour : Characteristic
- Odour threshold : No data available
- pH : No data available
- Relative evaporation rate (butylacetate=1) : No data available
- Melting point : No data available
- Freezing point : No data available

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Boiling point	: No data available
Flash point	: No data available
Self ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
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
Log Pow	: No data available
Log Kow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

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.

10.6. Hazardous decomposition products

Oxides of carbon when burned.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Triethylene glycol dimethacrylate (109-16-0)	
LD50 oral rat	10837 mg/kg
ATE (oral)	10837 mg/kg

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

Sodium fluoride (7681-49-4)	
LD50 oral rat	52 mg/kg
LD50 dermal rat	175 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

Sodium fluoride (7681-49-4)	
IARC group	3
National Toxicity Program (NTP) Status	1

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

Sodium fluoride (7681-49-4)	
LC50 fishes 1	> 530 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus)
EC50 Daphnia 1	338 mg/l (Exposure time: 48 h - Species: Daphnia magna)
EC50 other aquatic organisms 1	272 mg/l (Exposure time: 96 h - Species: Pseudokirchneriella subcapitata)
LC50 fish 2	830 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [semi-static])
EC50 Daphnia 2	98 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
EC50 other aquatic organisms 2	850 mg/l (Exposure time: 72 h - Species: Desmodesmus subspicatus [static])

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

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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.

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

Triethylene glycol dimethacrylate (109-16-0)
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

2-Propenoic acid, 2-methyl-, 1,6-hexanediyl ester (6606-59-3)
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

Sodium fluoride (7681-49-4)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

Poly(oxy-1,2-ethanediyl), .alpha.,.alpha.'-[(1-methylethylidene)di-4,1-phenylene]bis[.omega.-[(2-methyl-1-oxo-2-propenyl)oxy]- (41637-38-1)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. US State regulations

Sodium fluoride (7681-49-4)
U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

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SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
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
H301	Toxic if swallowed
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
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.

SDS US (GHS HazCom 2012)