

SECTION 1: Identification

1.1. Identification

Product form : Mixture
 Trade name : RE-GEN™ Flowable Composite Liner

1.2. Recommended use and restrictions on use

Use of the substance/mixture : Used as a liner in dental restorations

1.3. Supplier

Inter-Med, Inc. / Vista Dental Products
 2200 South Street
 Racine, WI 53404
 T: (877)-418-4782

1.4. Emergency telephone number

Emergency number : 800-424-9300 (North America)
 +1 (703) 527-3887 (International)

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS-US classification

Acute toxicity (oral) Category 3	Toxic if swallowed
Skin corrosion/irritation Category 1B	Causes severe skin burns and eye damage
Serious eye damage/eye irritation Category 1	Causes serious eye damage
Skin sensitization, Category 1	May cause an allergic skin reaction
Reproductive toxicity Category 1B	May damage fertility or the unborn child

2.2. GHS Label elements, including precautionary statements

GHS US labeling

Hazard pictograms (GHS US) :



Signal word (GHS US) :

Danger

Hazard statements (GHS US) :

Toxic if swallowed
 Causes severe skin burns and eye damage
 May cause an allergic skin reaction
 May damage fertility or the unborn child

Precautionary statements (GHS US) :

Obtain special instructions before use.
 Do not handle until all safety precautions have been read and understood.
 Do not breathe vapors. Wash hands thoroughly after handling.
 Do not eat, drink or smoke when using this product.
 Contaminated work clothing must not be allowed out of the workplace
 Wear eye protection, protective gloves.
 If swallowed: Immediately call a poison center or doctor
 If swallowed: rinse mouth. Do NOT induce vomiting
 If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
 If inhaled: Remove person to fresh air and keep comfortable for breathing
 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
 Immediately call a poison center or doctor
 If skin irritation or rash occurs: Get medical advice/attention.
 Wash contaminated clothing before reuse.
 Store locked up.
 Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

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2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHSUS)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS-US classification
Barium glass	(CAS-No.) 1304-28-5	40 - 80	Ox. Sol. 1, H271 Acute Tox. 3 (Oral), H301 Skin Corr. 1B, H314 Eye Dam. 1, H318
2-Propenoic acid, 2-methyl-, (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] ester	(CAS-No.) 1565-94-2	10 - 40	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Skin Sens. 1, H317
Triethylene glycol dimethacrylate	(CAS-No.) 109-16-0	10 - 30	Skin Sens. 1B, H317
Submicron Silica	(CAS-No.) 112945-52-5	1 - 15	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
Benzoic acid, 4-(dimethylamino)-, ethyl ester	(CAS-No.) 10287-53-3	0 - 2	Repr. 1B, H360

*Chemical name, CAS number and/or exact concentration have been withheld as a trade secret

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Give artificial respiration if necessary. If you feel unwell, seek medical advice.
- First-aid measures after skin contact : Wash off immediately and plentifully with water for at least 20 minutes. Take off immediately all contaminated clothing and wash it before reuse. Get immediate medical advice/attention.
- First-aid measures after eye contact : In case of eye contact, immediately rinse with clean water for 20-30 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical advice/attention.
- First-aid measures after ingestion : Rinse mouth. Do not induce vomiting. Seek immediate medical advice.

4.2. Most important symptoms and effects (acute and delayed)

- Symptoms/effects : May damage fertility or the unborn child.
- Symptoms/effects after inhalation : Inhalation of airborne droplets or aerosols may cause irritation of the respiratory tract.
- Symptoms/effects after skin contact : Causes severe burns. May cause an allergic skin reaction.
- Symptoms/effects after eye contact : Causes serious eye damage.
- Symptoms/effects after ingestion : Toxic if swallowed. May cause burns or irritation of the linings of the mouth, throat, and gastrointestinal tract.

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

- Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.
- Unsuitable extinguishing media : None known.

5.2. Specific hazards arising from the chemical

- Fire hazard : On combustion, forms: carbon oxides (CO and CO₂). Thermal decomposition can lead to the release of irritating gases and vapors.
- Explosion hazard : No direct explosion hazard.

5.3. Special protective equipment and precautions for fire-fighters

- Firefighting instructions : Exercise caution when fighting any chemical fire.
- Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Protective equipment : Use personal protective equipment as required. For further information refer to section 8: "Exposure controls/personal protection".
- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Do not attempt to take action without suitable protective equipment. In case of inadequate ventilation wear respiratory protection.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage.
- Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For disposal of residues refer to section 13: "Disposal considerations".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Ensure good ventilation of the work station. Wear personal protective equipment. Do not breathe vapors
- Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Wash contaminated clothing before reuse. Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in a well-ventilated place. Keep cool.
- Incompatible materials : Strong acids. Strong bases.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Barium glass (1304-28-5)		
Not applicable		
Methacrylate Monomers (1565-94-2)		
Not applicable		
Triethylene glycol dimethacrylate (109-16-0)		
Not applicable		
Submicron Silica (112945-52-5)		
OSHA	OSHA PEL (TWA) (mg/m ³)	80 mg/m ³
OSHA	OSHA PEL (TWA) (ppm)	20 ppm
NIOSH	NIOSH REL (TWA) (mg/m ³)	6 mg/m ³
Ethyl-4-dimethyl aminobenzoate (10287-53-3)		
Not applicable		

8.2. Appropriate engineering controls

- Appropriate engineering controls : Ensure good ventilation of the work station. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.
- Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

Hand protection:

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Impermeable protective gloves

Eye protection:

Safety glasses with side shields

Skin and body protection:

Long sleeved protective clothing

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Paste.
Color	: natural color
Odor	: Odorless
Odor threshold	: No data available
pH	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: Not applicable.
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Specific gravity / density	: > 1
Solubility	: No data available
Log Pow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable at ambient temperature and under normal conditions of use.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None known.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

No hazardous decomposition products known at room temperature.

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

- Acute toxicity (oral) : Toxic if swallowed.
Acute toxicity (dermal) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

ATE US (oral)	179 mg/kg body weight
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Barium glass (1304-28-5)

ATE US (oral)	100 mg/kg body weight
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Triethylene glycol dimethacrylate (109-16-0)

LD50 oral rat	10837 mg/kg
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Submicron Silica (112945-52-5)

LD50 oral rat	3160 mg/kg
LD50 dermal rabbit	> 2000 mg/kg

- Skin corrosion/irritation : Causes severe skin burns and eye damage.
Serious eye damage/irritation : Causes serious eye damage.
Respiratory or skin sensitization : May cause an allergic skin reaction.
Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity : Not classified (Based on available data, the classification criteria are not met)

Submicron Silica (112945-52-5)

IARC group	3 - Not classifiable
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- Reproductive toxicity : May damage fertility or the unborn child.
Specific target organ toxicity – single exposure : Not classified (Based on available data, the classification criteria are not met)

Submicron Silica (112945-52-5)

Specific target organ toxicity – single exposure	May cause respiratory irritation.
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- Specific target organ toxicity – repeated exposure : Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)
Viscosity, kinematic : No data available
Symptoms/effects : May damage fertility or the unborn child.
Symptoms/effects after inhalation : Inhalation of airborne droplets or aerosols may cause irritation of the respiratory tract.
Symptoms/effects after skin contact : Causes severe burns. May cause an allergic skin reaction.
Symptoms/effects after eye contact : Causes serious eye damage.
Symptoms/effects after ingestion : Toxic if swallowed. May cause burns or irritation of the linings of the mouth, throat, and gastrointestinal tract.

SECTION 12: Ecological information

12.1. Toxicity

- Ecology - general : This material has not been tested for environmental effects.

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

- Other information : Avoid release to the environment.

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SECTION 13: Disposal considerations

13.1. Disposal methods

- Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

- Transport document description : UN2922 Corrosive liquids, toxic, n.o.s., 8 (6.1), II
UN-No.(DOT) : UN2922
Proper Shipping Name (DOT) : Corrosive liquids, toxic, n.o.s.
Class (DOT) : 8 - Class 8 - Corrosive material 49 CFR 173.136
Packing group (DOT) : II - Medium Danger
Subsidiary risk (DOT) : 6.1 - Class 6.1 - Poisonous materials 49 CFR 173.132
Hazard labels (DOT) : 8 - Corrosive
6.1 - Poison



- DOT Packaging Non Bulk (49 CFR 173.xxx) : 202
DOT Packaging Bulk (49 CFR 173.xxx) : 243
DOT Special Provisions (49 CFR 172.102) : B3 - MC 300, MC 301, MC 302, MC 303, MC 305, and MC 306 and DOT 406 cargo tanks and DOT 57 portable tanks are not authorized.
IB2 - Authorized IBCs: Metal (31A, 31B and 31N); Rigid plastics (31H1 and 31H2); Composite (31HZ1). Additional Requirement: Only liquids with a vapor pressure less than or equal to 110 kPa at 50 C (1.1 bar at 122 F), or 130 kPa at 55 C (1.3 bar at 131 F) are authorized.
T7 - 4 178.274(d)(2) Normal..... 178.275(d)(3)
TP2 - a. The maximum degree of filling must not exceed the degree of filling determined by the following: (image) Where: tr is the maximum mean bulk temperature during transport, tf is the temperature in degrees celsius of the liquid during filling, and a is the mean coefficient of cubical expansion of the liquid between the mean temperature of the liquid during filling (tf) and the maximum mean bulk temperature during transportation (tr) both in degrees celsius. b. For liquids transported under ambient conditions may be calculated using the formula: (image) Where: d15 and d50 are the densities (in units of mass per unit volume) of the liquid at 15 C (59 F) and 50 C (122 F), respectively.
DOT Packaging Exceptions (49 CFR 173.xxx) : 154
DOT Quantity Limitations Passenger aircraft/rail : 1 L
(49 CFR 173.27)
DOT Quantity Limitations Cargo aircraft only (49 : 30 L
CFR 175.75)
DOT Vessel Stowage Location : B - (i) The material may be stowed "on deck" or "under deck" on a cargo vessel and on a passenger vessel carrying a number of passengers limited to not more than the larger of 25 passengers, or one passenger per each 3 m of overall vessel length; and (ii) "On deck only" on passenger vessels in which the number of passengers specified in paragraph (k)(2)(i) of this section is exceeded.
DOT Vessel Stowage Other : 40 - Stow "clear of living quarters"
Emergency Response Guide (ERG) Number : 154
Other information : No supplementary information available.

Transportation of Dangerous Goods

- Transport document description : UN2922 CORROSIVE LIQUID, TOXIC, N.O.S., 8 (6.1), II
UN-No. (TDG) : UN2922
Proper Shipping Name (Transportation of Dangerous Goods) : CORROSIVE LIQUID, TOXIC, N.O.S.
TDG Primary Hazard Classes : 8 - Class 8 - Corrosives
Packing group : II - Medium Danger
TDG Subsidiary Classes : 6.1

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TDG Special Provisions	: 16 - (1) The technical name of at least one of the most dangerous substances that predominantly contributes to the hazard or hazards posed by the dangerous goods must be shown, in parentheses, on the shipping document following the shipping name in accordance with clause 3.5(1)(c)(ii)(A) of Part 3 (Documentation). The technical name must also be shown, in parentheses, on a small means of containment or on a tag following the shipping name in accordance with subsections 4.11(2) and (3) of Part 4 (Dangerous Goods Safety Marks). (2) Despite subsection (1), the technical name for the following dangerous goods is not required to be shown on a shipping document or on a small means of containment when Canadian law for domestic transport or an international convention for international transport prohibits the disclosure of the technical name: (a) UN1544, ALKALOID SALTS, SOLID, N.O.S. or ALKALOIDS, SOLID, N.O.S; (b) UN1851, MEDICINE, LIQUID, TOXIC, N.O.S; (c) UN3140, ALKALOID SALTS, LIQUID, N.O.S. or ALKALOIDS, LIQUID, N.O.S; (d) UN3248, MEDICINE, LIQUID, FLAMMABLE, TOXIC, N.O.S; or (e) UN3249, MEDICINE, SOLID, TOXIC, N.O.S. An example in Canada is the "Food and Drugs Act". (3) Despite subsection (1), the technical name for the following dangerous goods is not required to be shown on a small means of containment: (a) UN2814, INFECTIOUS SUBSTANCE, AFFECTING HUMANS; or (b) UN2900, INFECTIOUS SUBSTANCE, AFFECTING ANIMALS. SOR/2014-306
Explosive Limit and Limited Quantity Index	: 1 L
Passenger Carrying Road Vehicle or Passenger Carrying Railway Vehicle Index	: 1 L

Transport by sea

Transport document description (IMDG)	: UN 2922 CORROSIVE LIQUID, TOXIC, N.O.S., 8 (6.1), II
UN-No. (IMDG)	: 2922
Proper Shipping Name (IMDG)	: CORROSIVE LIQUID, TOXIC, N.O.S.
Class (IMDG)	: 8 - Corrosive substances
Packing group (IMDG)	: II - substances presenting medium danger
Subsidiary risks (IMDG)	: 6.1 - Toxic substances

Air transport

Transport document description (IATA)	: UN 2922 Corrosive liquid, toxic, n.o.s., 8 (6.1), II
UN-No. (IATA)	: 2922
Proper Shipping Name (IATA)	: Corrosive liquid, toxic, n.o.s.
Class (IATA)	: 8 - Corrosives
Packing group (IATA)	: II - Medium Danger
Subsidiary hazards (IATA)	: 6.1 - Toxic substances

SECTION 15: Regulatory information

15.1. US Federal regulations

Barium glass (1304-28-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory
Methacrylate Monomers (1565-94-2)
Listed on the United States TSCA (Toxic Substances Control Act) inventory
Triethylene glycol dimethacrylate (109-16-0)
Listed on the United States TSCA (Toxic Substances Control Act) inventory
Ethyl-4-dimethyl aminobenzoate (10287-53-3)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. International regulations

CANADA

Barium glass (1304-28-5)
Listed on the Canadian DSL (Domestic Substances List)
Methacrylate Monomers (1565-94-2)
Listed on the Canadian DSL (Domestic Substances List)

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Triethylene glycol dimethacrylate (109-16-0)

Listed on the Canadian DSL (Domestic Substances List)

Submicron Silica (112945-52-5)

Listed on the Canadian DSL (Domestic Substances List)

Ethyl-4-dimethyl aminobenzoate (10287-53-3)

Listed on the Canadian DSL (Domestic Substances List)

EU-Regulations

Barium glass (1304-28-5)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

Methacrylate Monomers (1565-94-2)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

Triethylene glycol dimethacrylate (109-16-0)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

Ethyl-4-dimethyl aminobenzoate (10287-53-3)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

National regulations

Barium glass (1304-28-5)

Listed on the AICS (Australian Inventory of Chemical Substances)
Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)
Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory
Listed on the Japanese ISHL (Industrial Safety and Health Law)
Listed on the Korean ECL (Existing Chemicals List)
Listed on NZIoC (New Zealand Inventory of Chemicals)
Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)
Japanese Poisonous and Deleterious Substances Control Law
Listed on INSQ (Mexican National Inventory of Chemical Substances)
Listed on the TCSI (Taiwan Chemical Substance Inventory)

Methacrylate Monomers (1565-94-2)

Listed on the AICS (Australian Inventory of Chemical Substances)
Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)
Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory
Listed on the Japanese ISHL (Industrial Safety and Health Law)
Listed on the Korean ECL (Existing Chemicals List)
Listed on NZIoC (New Zealand Inventory of Chemicals)
Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)
Listed on the TCSI (Taiwan Chemical Substance Inventory)

Triethylene glycol dimethacrylate (109-16-0)

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Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)
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Ethyl-4-dimethyl aminobenzoate (10287-53-3)

Listed on the AICS (Australian Inventory of Chemical Substances)
Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)
Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory
Listed on the Japanese ISHL (Industrial Safety and Health Law)
Listed on the Korean ECL (Existing Chemicals List)
Listed on NZIoC (New Zealand Inventory of Chemicals)
Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)
Listed on the TCSI (Taiwan Chemical Substance Inventory)

15.3. US State regulations

No additional information available

SECTION 16: Other information

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Revision date : 4 March 2021

Full text of H-phrases:

H271	May cause fire or explosion; strong oxidizer
H301	Toxic if swallowed
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

SDS US (GHS HazCom 2012)

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.