

SAFETY DATA SHEETS

This SDS packet was issued with item:

076492516

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

076492003 076492011 076492029 076492037 076492045 076492052 076492060 076492078 076492086 076492094
076492102 076492110 076492128 076492136 076492144 076492151 076492169 076492177 076492185 076492193
076492219 076492227 076492409 076492417 076492425 076492433 076492441 076492458 076492466 076492474
076492482 076492490 076492508 076492524 076492532 076492540 076492557 076492565 076492573 076492581
076492599 076492607 076492623

1. Chemical Product and Contact Information
Product Name: Simile® nano-hybrid composite

Material Safety Sheet Number: 00203
 Date of Issue: 02/10/00
 Revision Date: 09/10/09

Company Identification: **Pentron Clinical**
 1717 West Collins Ave.
 Orange, CA 92867
 Phone: **800-551-0283**
 203-265-7397

Emergency Information Chemtrec: **800-424-9300**
Chemtrec International: **202-483-7616**
2. Composition/Information on Ingredients

Chemical characteristics: A mixture of difunctional methacrylates of PCBisGMA, BisGMA, UDMA and HDDMA, barium boro-silicate glass*, nano-particulated silica, zirconium silicate*, photoinitiator, accelerator, stabilizer, silane and pigments.
 *contains a small amount of Al₂O₃

Description: Same as above.

Hazardous components: None Known.

| Element | CAS # | Exposure Limit mg/m ³ | |
|---|-------------|----------------------------------|-----------|
| | | OSHA PEL | ACGIH TLV |
| PCBisGMA | N /A | N/E | N/E |
| BisGMA | 1565-94-2 | N/E | N/E |
| UDMA | 74389-53-0 | N/E | N/E |
| HDDMA | 6606-59-3 | N/E | N/E |
| Silane Treated Barium Boro-alumino Silicate Glass | N /A | N/E | N/E |
| Silane Treated Nano-particulated Silica | 112965-52-5 | Unknown | N/E |
| Zirconium Silicate | N /A | N/E | N/E |
| Pigments | Various | Unknown | Unknown |
| Photocuring system | Various | N/E | N/E |

3. Hazard Identification

Risk identification: None known.

Special risks for human beings and environment: People known to be allergic to methacrylate should avoid use of this material.

Classification: Classification corresponds to actual EEC guidelines.

4. First Aid Measures

General information:

After skin contact: Wash with plenty of water and soap.

After eye contact: Rinse with water and consult a physician.

After swallowing: Seek medical advice immediately.

5. Fire Fighting Measures

Extinguishing media: CO₂, water.

Protective equipment: Unknown.

6. Accidental Release Measures

Personal precautions: Protective gloves, goggles and others are recommended.

Environmental precautions: Unknown.

Methods for cleaning up: Wipe up with absorbent material.

Additional information: Unknown.

7. Handling and Storage

Storage: Store at ambient temperature. Protect from light source. Do not store in high heat areas. Store away from foodstuffs.

8. Exposure Controls/Personal Protection

| | |
|--|---|
| Personal protective equipment: | Protective gloves, goggles are recommended. |
| General measure of protection and hygiene: | Normal hygienic measures. |
| Respiration: | Not applicable. |
| Hands: | Protective gloves. |
| Eyes: | OSHA approved goggles. |

9. Physical and Chemical Properties

| | | |
|-------------|--------|-------------------------|
| Appearance: | Form: | Viscous paste |
| | Color: | Tooth colored. |
| | Odor: | Slight ester-like odor. |

Information on change in the physical state

| | |
|---------------------------------------|-------------------------------|
| Melting point/melting range: | Not applicable. |
| Boiling point/boiling range: | Not applicable. |
| Flash point: | Not applicable. |
| Autoignition temperature: | Unknown. |
| Danger of explosion: | Not likely. |
| Density: | c.a.1.8-1.9 g/cm ³ |
| Vapor pressure: | Not applicable. |
| Viscosity: | Paste. |
| pH: | Not applicable. |
| Solubility in/miscibility with water: | None. |
| Content of solvents: | None. |
| Organic solvents: | None. |
| Water: | None. |
| Content of solids: | >70% |

10. Stability and Reactivity

| | |
|--|---|
| | Stable. Avoid heat, direct sunlight. |
| Incompatibility with other substances: | Avoid peroxides, strong oxidizers, reducing agents and free radical initiators. |
| Hazardous decomposition products: | Not known. |

11. Toxicological Information

| | |
|---------------------------------------|---|
| | Allergic reaction to methacrylate by exposure to product is possible. |
| Acute toxicity: | Not available. |
| Primary irritation: | |
| Skin Contact: | Yes. |
| Skin absorption: | Unknown. |
| Eye: | Irritating. |
| Inhalation: | Not volatile. |
| Ingestion: | Possibly toxic when swallowed. |
| Sensitization of product: | Not observed. |
| Additional Toxicological information: | Non-mutagenic. |

12. Ecological Information

| | |
|---------------------------------------|----------|
| General information: | Unknown. |
| Classification of water endangerment: | Unknown. |

13. Disposal Considerations

| | |
|-------------------------|---|
| Product Recommendation: | Dispose in accordance with local, state, and federal regulations. |
| Disposal key number: | Unknown. |
| Uncleaned packaging: | Unknown. |
| Recommendation: | Unknown. |

14. Transport Information

| | |
|----------|---------------------------|
| RID/ADR: | Not a hazardous material. |
|----------|---------------------------|

15. Regulatory information

| | |
|---|---|
| Classification according to EEC guidelines: | No classification necessary to actual EEC guidelines. |
| National Prescriptions: | Unknown. |
| Classification according to VbF: | Not applicable. |

16. Other Information

The information and recommendations set forth herein (hereinafter "information") are presented in good faith and believed to be correct as of the date hereof. Pentron Clinical however, makes no representations as to the completeness or accuracy of this information and supplies it on the condition that the persons receiving same will make their own determination as to its suitability for their purposes prior to use. In no event will Pentron Clinical be responsible for damages of any nature whatsoever resulting from the use of or reliance upon information.

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SAFETY DATA SHEET

Section 1. Product And Company Identification

Product Name: Simile™ Universal Composite

Product Use: Dental product: Composite

Manufacturer: Pentron Clinical
1717 W. Collins Ave.
Orange, CA 92867-5422
U.S.A.

Information Phone Number: 1-800-841-1428 (Customer Service)

Chemical Emergency Phone Number (Chemical Spills, Leaks, Fire, Exposure or Accident only):
CHEMTREC 1-800-424-9300 (in the US) 1-703-527-3887 (Outside the US)

SDS Date Of Preparation/Revision: 06/24/19

Section 2. Hazards Identification

GHS Classification:

Skin Irritation Category 2

Eye Irritation Category 2A

Skin Sensitization Category 1

Label Elements:

Warning!



Hazard Phrases

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

Precautionary Phrases:

Do not breathe dust, fumes, vapors.

Wash hands thoroughly after handling.

Wear protective gloves, protective clothing, eye protection, face protection.

IF ON SKIN: Wash with plenty of soap and water. Take off contaminated clothing. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical attention.

IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention.

Store locked up.

Dispose of contents and container in accordance with local and national regulations.

Section 3. Composition/Information on Ingredients

| Component | CAS No. | Amount |
|--|------------|--------|
| 1,6-hexanediyl bismethacrylate | 6606-59-3 | 5-10% |
| 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate | 72869-86-4 | 5-10% |

Section 4. First Aid Measures

Inhalation: Remove victim to fresh air. Get medical attention if symptoms occur.

Skin Contact: Flush thoroughly with water. Get medical attention if irritation or symptoms of exposure develop. Remove and launder contaminated clothing before re-use.

Eye Contact: Rinse thoroughly with water. Get medical attention if irritation occurs and persists.

Ingestion: Do NOT induce vomiting. Rinse mouth with water. Never give anything by mouth to an unconscious or convulsing person. Keep the victim calm and warm. Get immediate medical attention.

Most important symptoms and effects, acute and delayed: Causes serious eye irritation and skin irritation. May cause an allergic skin reaction. Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.

Indication of immediate medical attention and special treatment, if needed: Immediate medical attention is not required.

Section 5. Fire Fighting Measures

Suitable (and Unsuitable) Extinguishing Media: Use any media appropriate for the surrounding fire. Cool fire exposed containers with water.

Specific Hazards Arising from the Chemical: Combustion may produce carbon dioxide, carbon monoxide, nitrogen oxides, and metal oxides.

Special Protective Equipment and Precautions for Fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for fires in areas where chemicals are used or stored. Cool fire-exposed containers with water. Contain water used in firefighting from entering sewers or natural waterways.

Section 6: Accidental Release Measures

Personal precautions, Protective equipment, and Emergency procedures: Evacuate spill area and keep unprotected personnel away. Avoid contact with eyes, skin and clothing. Wear appropriate protective clothing and equipment. Do not breathe dust or vapors.

Environmental Precautions: Avoid releases to the environment. Report spill as required by local and federal regulations.

Methods and Materials for Containment and Cleaning up: Prompt cleanup and removal are necessary. Absorb spills with an inert material and place in an appropriate waste disposal container.

Section 7. Handling and Storage

Precautions for Safe Handling: Prevent contact with eyes, skin and clothing. Always wear impervious gloves, chemical safety goggles and protective clothing when handling this material. Wash thoroughly with soap and water after handling. Do not eat, drink or smoke in the work area. Do not breathe dust or vapors. Use with adequate ventilation. Remove and wash contaminated clothing before reuse.

Empty containers retain product residues which can be hazardous. Follow all SDS precautions when handling empty containers.

Conditions for Safe Storage, Including any Incompatibilities: Store in a dry, well-ventilated area away from direct sunlight. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers.

Section 8. Exposure Controls / Personal Protection

Exposure Limits

| Chemical | Exposure Limit |
|--|------------------|
| 1,6-hexanediyl bismethacrylate | None Established |
| 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate | None Established |

Appropriate Engineering Controls: Use with adequate general or local exhaust ventilation to maintain exposure levels below the occupational exposure limits.

Respiratory Protection: In operations where exposure levels are exceeded, an approved dust/mist respirator or supplied air respirator should be used. Equipment selection depends on contaminant type and concentration. Select in accordance with applicable regulations and good industrial hygiene practice.

Hand protection: Impervious gloves are suggested to prevent skin contact. Contact your glove supplier for selection assistance.

Eye Protection: Chemical safety goggles are recommended if contact is possible.

Skin Protection: Wear protective clothing as needed to avoid skin contact and contamination of personal clothing.

Hygiene measures: Suitable eye and skin washing facilities should be available in the work area.

Section 9. Physical and Chemical Properties

| | | | |
|---|-------------------------|----------------------------------|--|
| Appearance: | Paste of various colors | Odor: | Fruity |
| Odor Threshold: | Not available | pH: | Not available |
| Melting/Freezing Point: | Not available | Boiling Point/Range: | Not available |
| Flash Point: | Not flammable | Evaporation Rate: | Not available |
| Flammability: (Solid, Gas) | Not applicable | Flammability Limits: | LEL: Not applicable UEL: Not applicable |
| Vapor Pressure: | Not available | Vapor Density: | Not available |
| Relative Density: | 1.8 – 1.9 | Solubilities: | Insoluble in water |
| Partition Coefficient: (N-Octanol/Water) | Not available | Autoignition Temperature: | Not available |
| Decomposition Temperature: | Not available | Viscosity: | Not available |

Section 10. Stability and Reactivity

Reactivity: The product is not expected to be reactive.

Chemical Stability: Stable under normal storage and handling conditions.

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

Conditions to avoid: Avoid heat and direct sunlight.

Incompatible Materials: Oxidizing materials, reducing materials, peroxide, and free radical initiators.

Hazardous decomposition products: None if stored normally.

Section 11. Toxicological Information

Potential Health Effects:

Inhalation: Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.

Skin Contact: Causes skin irritation. May cause an allergic skin reaction.

Eye Contact: Causes serious eye irritation.

Ingestion: None known.

Chronic Hazards: None known.

Skin Sensitization: No adverse effects expected. Product is classified as Grade I – weak sensitizer in Kligman test.

Respiratory Sensitization: No data available. This product is not expected to cause respiratory sensitization.

Germ Cell Mutagenicity: None of the components are mutagenic.

Carcinogen: None of the components are listed as a carcinogen or potential carcinogen by IARC, NTP, ACGIH, or OSHA.

Developmental / Reproductive Toxicity: None of the components have been shown to cause reproductive or developmental toxicity.

Specific Target Organ Toxicity (Single Exposure): Single exposure to 1,6-hexanediyl bismethacrylate and 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecane-1,16-diyl bismethacrylate may cause respiratory tract irritation.

Specific Target Organ Toxicity (Repeated Exposure): No data available.

Aspiration Toxicity: Not an aspiration hazard.

Acute Toxicity Values:

Product ATE: 3928.5 mg/kg (Oral)

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecane-1,16-diyl bismethacrylate:

LD50 Oral rat: >5000 mg/kg

Section 12. Ecological Information

Toxicity: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecane-1,16-diyl bismethacrylate: 72 hr EC50 *Desmodesmus subspicatus* >0.6 mg/L; 48 hr EC50 *Daphnia magna* >1.2 mg/L

Persistence and degradability: Biodegradation is not applicable to inorganic substances.

Bioaccumulative Potential:

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecane-1,16-diyl bismethacrylate: log P_{ow} 3, potential for bioaccumulative is low.

Mobility in Soil: No data available.

Other Adverse Effects: No data available.

Section 13. Disposal Considerations

Disposal: For unused solution, flush thoroughly with large quantities of water into sewage disposal system in accordance with Federal, State, and local regulations. For used solution, the waste solution must be characterized by the generator and disposed of in accordance with Federal, State, and local regulations.

Container Disposal: Rinse empty container thoroughly with water and discard clean, empty container as general trash or offer for recycling, if available.

Section 14. Transport Information

| | UN Number | UN Proper Shipping Name | Hazard Class(s) | Packing Group | Environmental Hazards |
|------------|-----------|-------------------------|-----------------|---------------|-----------------------|
| US DOT | None | Not Regulated | None | None | None |
| Canada TDG | None | Not Regulated | None | None | None |

| | | | | | |
|------------------|------|---------------|------|------|------|
| IMDG | None | Not Regulated | None | None | None |
| IATA/ICAO | None | Not Regulated | None | None | None |

Section 15. Regulatory Information

U.S. Federal Regulations:

EPA SARA 311/312 Hazard Classification: Refer to Section 2 for OSHA Hazard Classification.

EPA SARA 313: This Product Contains the Following Chemicals Subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None.

Protection Of Stratospheric Ozone: This product is not known to contain or to have been manufactured with ozone depleting substances as defined in 40 CFR Part 82, Appendix A to Subpart A.

CERCLA SECTION 103: This product is not subject to CERCLA reporting requirements; however, many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

US EPA TSCA Inventory: All of the components of this product are listed on the Toxic Substances Control Act (TSCA) Chemical Substances Inventory or exempt.

Canadian Regulations:

Canadian Environmental Protection Act: All of the components in this product are listed on the Domestic Substances List (DSL) or exempt.

National Pollutant Release Inventory (NPRI): This Product Contains the Following Chemicals Subject to Annual Release Reporting Requirements NPRI: None

International Inventories

Australia: All of the components in this product are listed on the Australian Inventory of Chemical Substances (AICS) or exempt.

China: All of the components in this product are listed on the Inventory of Existing Chemical Substances in China (IECSC) or exempt.

European Union: All the components in this product are listed on the EINECS inventory or exempt.

Korea: All of the components in this product are listed on the Korean Existing Chemicals List (KECL) or exempt.

New Zealand: All of the components in this product are listed on the New Zealand Inventory of Chemicals (NZIoC) or exempt.

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| Section 16. Other Information |
|--------------------------------------|

NFPA Rating: Fire: 0 Health: 2 Instability: 0

Effective Date: June 24, 2019

Supersedes Date: January 8, 2015

Revision Summary: All Sections – New SDS format

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