

SAFETY DATA SHEETS

This SDS packet was issued with item:

076492045

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 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 076492516 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.
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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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Section 1. Identification

GHS product identifier : Simile™ Universal Composite

Other means of identification : Not available.

Product type : Paste.

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

Product use : Dental product: Composite

Area of application : Professional applications.

Manufacturer : **Pentron Clinical**
1717 West Collins Avenue
Orange, CA 92867-5422
Telephone no.: 1-203-265-7397, Toll Free: 1-800-551-0283

e-mail address of person responsible for this SDS : edwin.varela@kavokerrgroup.com

Emergency telephone number (with hours of operation) : CHEMTREC® (24 hours) U.S. : 1-800-424-9300 International: +1-703-527-3887

Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Health effects are based on the uncured material.

Classification of the substance or mixture : SKIN IRRITATION - Category 2
EYE IRRITATION - Category 2A

Percentage of the mixture consisting of ingredient(s) of unknown toxicity: 96%

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : Causes serious eye irritation.
Causes skin irritation.

Precautionary statements

Prevention : Wear protective gloves. Wear eye or face protection. Wash hands thoroughly after handling.

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

Section 2. Hazards identification

Storage	: Not applicable.
Disposal	: Not applicable.
Hazards not otherwise classified	: None known.

Section 3. Composition/information on ingredients

Substance/mixture	: Mixture
Other means of identification	: Not available.

CAS number/other identifiers

CAS number	: Not applicable.
Product code	: Not available.

Ingredient name	Other names	%	CAS number
1,6-hexanediyl bismethacrylate	1,6-hexanediyl bismethacrylate	5-10	6606-59-3
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	5-10	72869-86-4

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health and hence require reporting in this section.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact	: No special measures are required. In case of contact with eyes, rinse immediately with plenty of water. Get medical attention if symptoms occur.
Inhalation	: No special measures required. If inhaled, remove to fresh air. Get medical attention if symptoms occur.
Skin contact	: No special measures required. In case of contact, immediately flush skin with plenty of water. Get medical attention if symptoms occur.
Ingestion	: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Get medical attention if adverse health effects persist or are severe.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact	: Causes serious eye irritation.
Inhalation	: Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
Skin contact	: Causes skin irritation.
Ingestion	: No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact	: Adverse symptoms may include the following: pain or irritation watering redness
Inhalation	: No specific data.

Section 4. First aid measures

- Skin contact** : Adverse symptoms may include the following:
irritation
redness
- Ingestion** : No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : In case of major fire and large quantities: No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : Do not use water jet.

Specific hazards arising from the chemical : No specific fire or explosion hazard.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
metal oxide/oxides

Special protective actions for fire-fighters : In case of major fire and large quantities: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : Low release. For professional use only. Handling of product in very small amounts or in situations where release is highly unlikely
- For emergency responders** : Low release. See also the information in "For non-emergency personnel".

Environmental precautions : Low release. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

- Small spill** : Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container.
- Large spill** : Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container.

Section 7. Handling and storage

Precautions for safe handling

- Protective measures** : No special measures are required for small quantities under normal and intended conditions of product use. For professional use only. Put on appropriate personal protective equipment (see Section 8). Handle with care and dispose in a safe manner.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.
- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

None.

- Appropriate engineering controls** : No special measures are required for small quantities under normal and intended conditions of product use.
- Environmental exposure controls** : No special measures are required for small quantities under normal and intended conditions of product use.
- Individual protection measures**
- Hygiene measures** : No special measures are required for small quantities under normal and intended conditions of product use.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.
- Skin protection**
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- Body protection** : No special measures are required for small quantities under normal and intended conditions of product use.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : No special measures are required for small quantities under normal and intended conditions of product use.

Section 9. Physical and chemical properties

Appearance

Physical state	: Solid. [Paste.]
Color	: Various
Odor	: Fruity ester-like
Odor threshold	: Not available.
pH	: Not available.
Melting point	: Not available.
Boiling point	: Not available.
Flash point	: Not available.
Evaporation rate	: Not available.
Flammability (solid, gas)	: Not available.
Lower and upper explosive (flammable) limits	: Not available.
Vapor pressure	: Not available.
Vapor density	: Not available.
Relative density	: Not available.
Solubility	: Insoluble in the following materials: cold water and hot water.
Solubility in water	: Not available.
Partition coefficient: n-octanol/water	: Not available.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
SADT	: Not available.
Viscosity	: Not available.
Density	: 1.8 to 1.9 g/cm ³

Section 10. Stability and reactivity

Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	: The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur. Under normal conditions of storage and use, hazardous polymerization will not occur.
Conditions to avoid	: Keep away from heat and direct sunlight.
Incompatible materials	: Reactive or incompatible with the following materials: oxidizing materials and reducing materials. Peroxide. free radical initiators
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Not available.

Conclusion/Summary : Based on the criteria of the protocol, this product is considered non-cytotoxic per ISO 10993-5.
Based on analysis and test results, this product is considered as biocompatible per EN ISO 7405:2008 and EN ISO 10993-1:2009.

Irritation/Corrosion

Not available.

Sensitization

Not available.

Conclusion/Summary

Skin : Kligman score: Grade I (weak sensitizer)

Mutagenicity

Not available.

Conclusion/Summary : Not mutagenic in Ames test.

Carcinogenicity

Not available.

Reproductive toxicity

Not available.

Teratogenicity

Not available.

Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
1,6-hexanediyl bismethacrylate	Category 3	Not applicable.	Respiratory tract irritation
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	Category 3	Not applicable.	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely routes of exposure : Routes of entry anticipated: Oral, Dermal, Inhalation.

Potential acute health effects

Eye contact : Causes serious eye irritation.
Inhalation : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
Skin contact : Causes skin irritation.
Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Section 11. Toxicological information

- Eye contact** : Adverse symptoms may include the following:
pain or irritation
watering
redness
- Inhalation** : No specific data.
- Skin contact** : Adverse symptoms may include the following:
irritation
redness
- Ingestion** : No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

- Potential immediate effects** : Not available.
- Potential delayed effects** : Not available.

Long term exposure

- Potential immediate effects** : Not available.
- Potential delayed effects** : Not available.

Potential chronic health effects

Not available.

- General** : No known significant effects or critical hazards.
- Carcinogenicity** : No known significant effects or critical hazards.
- Mutagenicity** : No known significant effects or critical hazards.
- Teratogenicity** : No known significant effects or critical hazards.
- Developmental effects** : No known significant effects or critical hazards.
- Fertility effects** : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
Oral	3928.5 mg/kg

Section 12. Ecological information

Toxicity

Not available.

Persistence and degradability

Not available.

Bioaccumulative potential

Section 12. Ecological information

Product/ingredient name	LogP _{ow}	BCF	Potential
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	3	-	low

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.
Additional information	-	-	-

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code : Not available.

Section 15. Regulatory information

U.S. Federal regulations : TSCA 8(a) PAIR: mequinol
 United States inventory (TSCA 8b): All components are listed or exempted.

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Immediate (acute) health hazard

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
1,6-hexanediyl bismethacrylate	5-10	No.	No.	Yes.	Yes.	No.
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	5-10	No.	No.	Yes.	Yes.	No.

SARA 313

Not applicable.

State regulations

Massachusetts : The following components are listed: MINERAL WOOL FIBER

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : None of the components are listed.

California Prop. 65

None of the components are listed.

Section 16. Other information

Hazardous Material Information System (U.S.A.)

Health	*	2
Flammability		0
Physical hazards		0

Section 16. Other information

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings are not required on SDSs under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered mark of the National Paint & Coatings Association (NPCA). HMIS® materials may be purchased exclusively from J. J. Keller (800) 327-6868.

The customer is responsible for determining the PPE code for this material.

National Fire Protection Association (U.S.A.)



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Copyright ©2001, National Fire Protection Association, Quincy, MA 02269. This warning system is intended to be interpreted and applied only by properly trained individuals to identify fire, health and reactivity hazards of chemicals. The user is referred to certain limited number of chemicals with recommended classifications in NFPA 49 and NFPA 325, which would be used as a guideline only. Whether the chemicals are classified by NFPA or not, anyone using the 704 systems to classify chemicals does so at their own risk.

History

Date of issue/Date of revision : 01/08/2015

Date of previous issue : No previous validation

Version : 1

Prepared by : IHS

Key to abbreviations :

- ATE = Acute Toxicity Estimate
- BCF = Bioconcentration Factor
- GHS = Globally Harmonized System of Classification and Labelling of Chemicals
- IATA = International Air Transport Association
- IBC = Intermediate Bulk Container
- IMDG = International Maritime Dangerous Goods
- LogPow = logarithm of the octanol/water partition coefficient
- MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
- UN = United Nations

References : HCS (U.S.A.)- Hazard Communication Standard
International transport regulations

▣ Indicates information that has changed from previously issued version.

Notice to reader

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