# SAFETY DATA SHEET

Simile™ Universal Composite

## Section 1. Identification

<table>
<thead>
<tr>
<th>GHS product identifier</th>
<th>: Simile™ Universal Composite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other means of identification</td>
<td>: Not available.</td>
</tr>
<tr>
<td>Product type</td>
<td>: Paste.</td>
</tr>
</tbody>
</table>

### 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

![Warning]

### 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.

Date of issue/Date of revision : 01/08/2015  
Date of previous issue : No previous validation  
Version : 1  
United States
Section 2. Hazards identification

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

Section 3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance/mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other means of identification</td>
<td>Not available.</td>
</tr>
</tbody>
</table>

**CAS number/other identifiers**

<table>
<thead>
<tr>
<th>CAS number</th>
<th>Other names</th>
<th>%</th>
<th>CAS number</th>
</tr>
</thead>
<tbody>
<tr>
<td>6606-59-3</td>
<td>1,6-hexanediyl bismethacrylate</td>
<td>5-10</td>
<td></td>
</tr>
<tr>
<td>72869-86-4</td>
<td>7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate</td>
<td>5-10</td>
<td></td>
</tr>
</tbody>
</table>

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
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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td></td>
</tr>
<tr>
<td>Physical state</td>
<td>Solid. [Paste.]</td>
</tr>
<tr>
<td>Color</td>
<td>Various</td>
</tr>
<tr>
<td>Odor</td>
<td>Fruity ester-like</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>Not available.</td>
</tr>
<tr>
<td>pH</td>
<td>Not available.</td>
</tr>
<tr>
<td>Melting point</td>
<td>Not available.</td>
</tr>
<tr>
<td>Boiling point</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not available.</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Lower and upper explosive (flammable) limits</td>
<td>Not available.</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>Not available.</td>
</tr>
<tr>
<td>Vapor density</td>
<td>Not available.</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not available.</td>
</tr>
<tr>
<td>Solubility</td>
<td>Insoluble in the following materials: cold water and hot water.</td>
</tr>
<tr>
<td>Solubility in water</td>
<td>Not available.</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not available.</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>Not available.</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>Not available.</td>
</tr>
<tr>
<td>SADT</td>
<td>Not available.</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not available.</td>
</tr>
<tr>
<td>Density</td>
<td>1.8 to 1.9 g/cm³</td>
</tr>
</tbody>
</table>

## Section 10. Stability and reactivity

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Category</th>
<th>Route of exposure</th>
<th>Target organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,6-hexanediyl bismethacrylate</td>
<td>Category 3</td>
<td>Not applicable.</td>
<td>Respiratory tract irritation</td>
</tr>
<tr>
<td>7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diy bismethacrylate</td>
<td>Category 3</td>
<td>Not applicable.</td>
<td>Respiratory tract irritation</td>
</tr>
</tbody>
</table>

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**

<table>
<thead>
<tr>
<th>Route</th>
<th>ATE value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>3928.5 mg/kg</td>
</tr>
</tbody>
</table>

Section 12. Ecological information

**Toxicity**
Not available.

**Persistence and degradability**
Not available.

**Bioaccumulative potential**

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Section 12. Ecological information

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>LogPow</th>
<th>BCF</th>
<th>Potential</th>
</tr>
</thead>
<tbody>
<tr>
<td>7,7,9(or 7,9,9)-trimethyl-4, 13-dioxo-3,14-dioxo-5, 12-diazahexadecane-1, 16-diyld bismethacrylate</td>
<td>3</td>
<td>-</td>
<td>low</td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>DOT Classification</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN proper shipping name</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Transport hazard class(es)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Packing group</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Environmental hazards</td>
<td>No.</td>
<td>No.</td>
</tr>
<tr>
<td>Additional information</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**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)
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

<table>
<thead>
<tr>
<th>Name</th>
<th>%</th>
<th>Fire hazard</th>
<th>Sudden release of pressure</th>
<th>Reactive</th>
<th>Immediate (acute) health hazard</th>
<th>Delayed (chronic) health hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,6-hexanediyl bismethacrylate 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyi bismethacrylate</td>
<td>5-10</td>
<td>No.</td>
<td>No.</td>
<td>Yes.</td>
<td>Yes.</td>
<td>No.</td>
</tr>
<tr>
<td></td>
<td>5-10</td>
<td>No.</td>
<td>No.</td>
<td>Yes.</td>
<td>Yes.</td>
<td>No.</td>
</tr>
</tbody>
</table>

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.)

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Physical hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>* 2</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

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United States
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.)

HMIS® Ratings:
- Flammability: 0
- Health: 2
- Instability/Reactivity: 0
- Special:

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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
- UN = United Nations

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

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.