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).

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 : ![Exclamation Mark]

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

<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>Ingredient name</th>
<th>Other names</th>
<th>%</th>
<th>CAS number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,6-hexanediyl bismethacrylate</td>
<td>1,6-hexanediyl bismethacrylate</td>
<td>5-10</td>
<td>6606-59-3</td>
</tr>
<tr>
<td>7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate</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>72869-86-4</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 resaled 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/cm³

### 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)

<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 l 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

Date of issue/Date of revision: 01/08/2015  Date of previous issue: No previous validation  Version: 1  6/10

United States
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

Date of issue/Date of revision: 01/08/2015  Date of previous issue: No previous validation  Version: 1

United States
Section 12. Ecological information

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>LogP&lt;sub&gt;ow&lt;/sub&gt;</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-diyldiisobutyl bis methacrylate</td>
<td>3</td>
<td>-</td>
<td>low</td>
</tr>
</tbody>
</table>

Mobility in soil

Soil/water partition coefficient (K<sub>oc</sub>): 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**

**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**

<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</td>
<td>5-10</td>
<td>No.</td>
<td>No.</td>
<td>Yes.</td>
<td>Yes.</td>
<td>No.</td>
</tr>
<tr>
<td>7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diy1 bismethacrylate</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>

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

**Date of previous issue**: No previous validation

**Version**: 1

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.)

Fire Protection

Flammability

Health 2 0

Instability/Reactivity

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

Indicates information that has changed from previously issued version.

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.