1. Identification of the material and supplier

**Names**
- Product name: Simile™ Universal Composite
- ADG: Not regulated.
- Manufacturer: Pentron Clinical  
  Unit 10, 112-118 Talavera Road  
  North Ryde, NSW 2113  
  Australia  
  Telephone no.: 1 800 643 603  
  Email general queries: kerraust.orders@sybrondental.com  
  Email technical queries: peter.green@sybrondental.com  
- Emergency telephone number: 61 401 690 670 (24 hours)

**Uses**
- Area of application: Professional applications.
- Material uses: Dental product: Composite
- Product type: Paste.

2. Hazards identification

**Classification**: Not regulated.
- Risk phrases: Not classified.
- Statement of hazardous/dangerous nature: NON-HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS.

Health effects are based on the uncured material.

3. Composition/information on ingredients

**Mixture**: Yes.

<table>
<thead>
<tr>
<th>Ingredient name</th>
<th>CAS number</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>glass, oxide, chemicals</td>
<td>65997-17-3</td>
<td>30-60</td>
</tr>
<tr>
<td>Silica, amorphous, fumed, cryst.-free</td>
<td>112945-52-5</td>
<td>&lt;10</td>
</tr>
</tbody>
</table>

Other ingredients, determined not to be hazardous according to Safe Work Australia criteria, and not dangerous according to the ADG Code, make up the product concentration to 100%.

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 or the environment and hence require reporting in this section.

4. First-aid measures

**First-aid measures**
- **Inhalation**: No special measures required. If inhaled, remove to fresh air. 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.
- **Skin contact**: No special measures required. In case of contact, immediately flush skin with plenty of water. Get medical attention if symptoms occur.
4. 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.

**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.

**Advice to doctor**: 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.

5. Fire-fighting measures

**Extinguishing media**

<table>
<thead>
<tr>
<th>Suitable</th>
<th>Not suitable</th>
<th>Special exposure hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use an extinguishing agent suitable for the surrounding fire.</td>
<td>None known.</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No specific fire or explosion hazard.</td>
</tr>
</tbody>
</table>

**Hazardous thermal decomposition products**: Decomposition products may include the following materials:
- Carbon dioxide
- Carbon monoxide
- Nitrogen oxides
- Metal oxide/oxides

**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.

6. Accidental release measures

**Personal precautions**: Low release. For professional use only. Handling of product in very small amounts or in situations where release is highly unlikely

**Environmental precautions**: Low release. Avoid dispersal of spilt 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 for cleaning up**

<table>
<thead>
<tr>
<th>Small spill</th>
<th>Large spill</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container.</td>
<td>Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container.</td>
</tr>
</tbody>
</table>

7. Handling and storage

**Handling**: 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 of in a safe manner.

**Storage**: 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 unlabelled containers. Use appropriate containment to avoid environmental contamination.

**Combustible liquid**: Not applicable.
8. Exposure controls/personal protection

Occupational exposure limits

<table>
<thead>
<tr>
<th>Ingredient name</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>glass, oxide, chemicals</td>
<td>ACGIH TLV (United States, 6/2013).</td>
</tr>
<tr>
<td></td>
<td>TWA: 5 mg/m³ 8 hours. Form: Inhalable fraction</td>
</tr>
<tr>
<td></td>
<td>TWA: 1 f/cc 8 hours. Form: Respirable fibers: length greater than 5 μM; aspect ratio equal to or greater than 3:1 as determined by the membrane filter method at 400-450X magnification (4-mm objective) phase contrast illumination.</td>
</tr>
<tr>
<td>Silica, amorphous, fumed, cryst.-free</td>
<td>Safe Work Australia (Australia, 7/2012).</td>
</tr>
<tr>
<td></td>
<td>TWA: 10 mg/m³ 8 hours. Form: Inhalable fraction</td>
</tr>
</tbody>
</table>

Recommended monitoring procedures: If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to appropriate monitoring standards. Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

Exposure controls

Engineering measures: No special measures are required for small quantities under normal and intended conditions of product use.

Hygiene measures: No special measures are required for small quantities under normal and intended conditions of product use.

Eyes: 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 or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Hands: 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.

Respiratory: No special measures are required for small quantities under normal and intended conditions of product use.

Skin: 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.

9. Physical and chemical properties

<table>
<thead>
<tr>
<th>Physical state</th>
<th>Solid. [Paste.]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>Various</td>
</tr>
<tr>
<td>Odour</td>
<td>Fruity ester-like</td>
</tr>
<tr>
<td>Boiling point</td>
<td>Not available.</td>
</tr>
<tr>
<td>Melting point</td>
<td>Not available.</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not available.</td>
</tr>
<tr>
<td>Density</td>
<td>1.8 to 1.9 g/cm³</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flammable limits</td>
<td>Not available.</td>
</tr>
<tr>
<td>Vapour density</td>
<td>Not available.</td>
</tr>
<tr>
<td>pH</td>
<td>Not available.</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not available.</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>Not available.</td>
</tr>
</tbody>
</table>
9. Physical and chemical properties

Solubility: Insoluble in the following materials: cold water and hot water.

10. Stability and reactivity

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 polymerisation will not occur.
Conditions to avoid: Keep away from heat and direct sunlight.
Materials to avoid: 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.

11. Toxicological information

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

Acute toxicity

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>Result</th>
<th>Species</th>
<th>Dose</th>
<th>Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silica, amorphous, fumed, cryst.-free</td>
<td>LD50 Oral</td>
<td>Rat</td>
<td>3160 mg/kg</td>
<td>-</td>
</tr>
</tbody>
</table>

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.

Potential chronic health effects

Chronic toxicity: Not available.
Irritation/Corrosion: Not available.
Sensitiser: Kligman score: Grade I (weak sensitizer)

Carcinogenicity

Conclusion/Summary: Not available.
Mutagenicity: Not mutagenic in Ames test.
Teratogenicity: Not available.
Reproductive toxicity: Not available.

Chronic effects: No known significant effects or critical hazards.
Carcinogenicity: No known significant effects or critical hazards.
11. Toxicological information

**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.

**Over-exposure signs/symptoms**
- **Inhalation** : No specific data.
- **Ingestion** : No specific data.
- **Skin** : No specific data.
- **Eyes** : No specific data.
- **Target organs** : Contains material which may cause damage to the following organs: upper respiratory tract, skin, eye, lens or cornea.

12. Ecological information

**Ecotoxicity** : No known significant effects or critical hazards.

**Aquatic ecotoxicity**
- **Conclusion/Summary** : Not available.

**Other ecological information**
- **Persistence/degradability**
  - **Conclusion/Summary** : Not available.

13. Disposal considerations

**Methods of disposal** : The generation of waste should be avoided or minimised 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.

14. Transport information

**International transport regulations**
- **ADG/ADR/IMDG/IATA** : Not regulated.

15. Regulatory information

**Standard Uniform Schedule of Medicine and Poisons**
- Not regulated.

**Control of Scheduled Carcinogenic Substances**
- No listed substance

**Australia inventory (AICS)** : Not determined.
**EU Classification** : Not classified.
16 . Other information

Person who prepared the MSDS : IHS
Date of previous issue : No previous validation.
Date of issue/ Date of revision : 1/08/2015.
Version : 1

Indicates information that has changed from previously issued version.

Disclaimer
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.