Section 1. Identification

Product name: Artiste® Nano 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

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

Emergency telephone number (with hours of operation): 61 401 690 670 (24 hours)
e-mail address of person responsible for this SDS: peter.green@sybrondental.com

Section 2. Hazards identification

HSNO Classification:
6.1 - ACUTE TOXICITY (oral) - Category E
6.3 - SKIN IRRITATION - Category A
6.4 - EYE IRRITATION - Category A (Irritant)

Percentage of the mixture consisting of ingredient(s) of unknown toxicity: 93.2%
Percentage of the mixture consisting of ingredient(s) of unknown hazards to the aquatic environment: 98.2%

Health effects are based on the uncured material.

This material is classified as hazardous according to criteria in the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001 and has been classified according to the Hazardous Substances (Classifications) Regulations 2001.

This material is not classified as a dangerous good according to criteria in New Zealand Standard 5433:2007 Transport of Dangerous Goods on Land.

GHS label elements

Signal word: Warning

Hazard statements:
May be harmful if swallowed.
Causes skin irritation.
Causes serious eye irritation.

Precautionary statements

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

Response:
IF ON SKIN: Take off contaminated clothing and wash before reuse. Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/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 advice/attention. Wash hands after handling. Call a POISON CENTER or doctor/physician if you feel unwell.

Storage:
Not applicable.

Disposal:
Not applicable.

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New Zealand
Section 2. Hazards identification

Symbol:

Other hazards which do not result in classification: None known.

Section 3. Composition/information on ingredients

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

**CAS number/other identifiers**

<table>
<thead>
<tr>
<th>Ingredient name</th>
<th>%</th>
<th>CAS number</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]bismethacrylate</td>
<td>&gt;=5 - &lt;10</td>
<td>1565-94-2</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>&gt;=5 - &lt;10</td>
<td>72869-86-4</td>
</tr>
<tr>
<td>1,6-hexanediyl bismethacrylate</td>
<td>&gt;=5 - &lt;10</td>
<td>6606-59-3</td>
</tr>
<tr>
<td>Silica, amorphous, fumed, cryst.-free</td>
<td>&gt;=5 - &lt;10</td>
<td>112945-52-5</td>
</tr>
</tbody>
</table>

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.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First-aid measures

**Description of necessary 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.

**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.

**Most important symptoms/effects, acute and delayed**

**Potential acute health effects**

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

**Ingestion**: May be harmful if swallowed.

**Skin contact**: Causes skin irritation.

**Eye contact**: Causes serious eye irritation.

**Over-exposure signs/symptoms**

<table>
<thead>
<tr>
<th>Inhalation</th>
<th>Ingestion</th>
<th>Skin</th>
</tr>
</thead>
<tbody>
<tr>
<td>No specific data.</td>
<td>No specific data.</td>
<td>Adverse symptoms may include the following: irritation, redness</td>
</tr>
</tbody>
</table>

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Section 4. First-aid measures

Eyes
Adverse symptoms may include the following:
- pain or irritation
- watering
- redness

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

Specific treatments
Not available.

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.

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. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

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
Not available.

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. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

Section 5. Fire-fighting measures

Extinguishing media
- Suitable: Use an extinguishing agent suitable for the surrounding fire.
- Not suitable: None known.

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

Hazchem code
Not available.

Special precautions 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

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 and material 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
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.

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Section 7. Handling and storage

**Conditions for safe storage, including any incompatibilities**

Store between the following temperatures: 20 to 25°C (68 to 77°F). 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.

Section 8. Exposure controls/personal protection

**Control parameters**

**Occupational exposure limits**

<table>
<thead>
<tr>
<th>Ingredient name</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silica, amorphous, fumed, cryst.-free</td>
<td>EH40/2005 WELs (United Kingdom (UK), 12/2011). TWA: 6 mg/m³ 8 hours. Form: inhalable dust TWA: 2.4 mg/m³ 8 hours. Form: respirable dust</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.

**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.

**Respiratory protection**

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

**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.

**Eye 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**

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.]

**Colour**

Various

**Odour**

Fruity ester-like

**Odour threshold**

Not available.
Section 9. Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<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>Burning rate</td>
<td>Not available.</td>
</tr>
<tr>
<td>Burning time</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>Vapour pressure</td>
<td>Not available.</td>
</tr>
<tr>
<td>Vapour density</td>
<td>Not available.</td>
</tr>
<tr>
<td>Relative density</td>
<td>1.8 to 1.9</td>
</tr>
<tr>
<td>Solubility</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>Aerosol product</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Type of aerosol</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Heat of combustion</td>
<td>Not available.</td>
</tr>
<tr>
<td>Ignition distance</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Enclosed space ignition - Time equivalent</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Enclosed space ignition - Deflagration density</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Flame height</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Flame duration</td>
<td>Not applicable.</td>
</tr>
</tbody>
</table>

Section 10. Stability and reactivity

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<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>Conditions to avoid</td>
<td>Keep away from heat and direct sunlight. Initiators.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Reactive or incompatible with the following materials: oxidizing materials and reducing materials. Peroxide.</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>Under normal conditions of storage and use, hazardous decomposition products should not be produced. Under normal conditions of storage and use, hazardous polymerisation will not occur.</td>
</tr>
</tbody>
</table>

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### Section 11. Toxicological information

#### Information on the likely routes of exposure

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

**Ingestion**: May be harmful if swallowed.

**Skin contact**: Causes skin irritation.

**Eye contact**: Causes serious eye irritation.

#### Symptoms related to the physical, chemical and toxicological characteristics

**Inhalation**: No specific data.

**Ingestion**: No specific data.

**Skin contact**: Adverse symptoms may include the following:

- irritation
- redness

**Eye contact**: Adverse symptoms may include the following:

- pain or irritation
- watering
- redness

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

##### 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 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.

**Sensitisation**

Not available.

**Conclusion/Summary**

**Skin**: Kligman score: Grade I (weak sensitizer)

#### Potential chronic health effects

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

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

**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.

**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.

#### Chronic toxicity

Not available.

**Carcinogenicity**

Not available.

**Mutagenicity**

Not available.

**Conclusion/Summary**

**Teratogenicity**: No mutagenic effect.

---

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Section 11. Toxicological information

Not available.

**Reproductive toxicity**
Not available.

**Specific target organ toxicity**
Not available.

**Aspiration hazard**
Not available.

**Numerical measures of toxicity**

<table>
<thead>
<tr>
<th>Route</th>
<th>ATE value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>4310 mg/kg</td>
</tr>
</tbody>
</table>

Section 12. Ecological information

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

**Aquatic and terrestrial toxicity**
Not available.

**Persistence/degradability**
Not available.

**Bioaccumulative potential**

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>Log$P_{ow}$</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-diyl bismethacrylate</td>
<td>3</td>
<td>-</td>
<td>low</td>
</tr>
</tbody>
</table>

**Mobility in soil**
Not available.

**Bioaccumulative potential**

<table>
<thead>
<tr>
<th>Other adverse effects</th>
<th>No known significant effects or critical hazards.</th>
</tr>
</thead>
</table>

Section 13. Disposal considerations

**Disposal methods**
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.

Section 14. Transport information

<table>
<thead>
<tr>
<th>Regulatory information</th>
<th>UN number</th>
<th>Proper shipping name</th>
<th>Classes</th>
<th>PG*</th>
<th>Label</th>
<th>Additional information</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Zealand Class</td>
<td>Not regulated</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>ADG Class</td>
<td>Not regulated</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>UN Class</td>
<td>Not regulated</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>ADR/RID Class</td>
<td>Not regulated</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Version : 1
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New Zealand
Section 14. Transport information

| IATA Class | Not regulated. | - | - | - | - |
| IMDG Class | Not regulated. | - | - | - | - |

PG*: Packing group

Section 15. Regulatory information

New Zealand Inventory of Chemicals (NZIoC): Not determined.

HSNO Approval Number: Not available.

HSNO Group Standard: Not available.

HSNO Classification:
6.1 - ACUTE TOXICITY (oral) - Category E
6.3 - SKIN IRRITATION - Category A
6.4 - EYE IRRITATION - Category A (Irritant)

Australia inventory (AICS): Not determined.

Safety, health and environmental regulations specific for the product: No known specific national and/or regional regulations applicable to this product (including its ingredients).

Section 16. Other information

History
Date of issue/Date of revision: 10/9/2014.
Date of previous issue: No previous validation.
Version: 1
Prepared by: IHS

Key to abbreviations:
ADN = European Provisions concerning the International Carriage of Dangerous Goods by Inland Waterway
ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road
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
RID = The Regulations concerning the International Carriage of Dangerous Goods by Rail
UN = United Nations

References:
GHS - Globally Harmonized System of Classification and Labeling of Chemicals
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.