1. IDENTIFICATION OF DANGEROUS SUBSTANCES AND IDENTIFICATION OF THE COMPANY

Product name: PREMIOTemp, PMMA BLOCK for CAD/CAM milling

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2. INFORMATION ON COMPOSITION AND SUBSTANCES

Polymethylmethacrylate with high molecular weight Methylmethacrylate
Pigments: Iron oxide and Titanium dioxide

<table>
<thead>
<tr>
<th>Hazardous Components</th>
<th>C.A.S. #</th>
<th>EINECS #</th>
<th>Substance Classification</th>
<th>WT %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methyl methacrylate</td>
<td>000080-62-6</td>
<td>201-297-2</td>
<td>Not Applicable</td>
<td>&lt;1.5</td>
</tr>
</tbody>
</table>

3. HAZARDS IDENTIFICATION

Product classification
May cause sensitisation by skin contact.

Health Hazard
The product presents no toxic hazard when used according the manufacturer's instructions. If a patient is known to be allergic to any of the ingredients of the teeth, the product should not be used.

Additional dangers to humans and the environment
See point 12.

4. FIRST AID MEASURES

General information
None.

After inhalation
In case of trouble after inhaling abrasive dust, seek medical advice.

After eye contact
In case of mechanical eye irritation, rinse thoroughly with large amounts of water. Consult a doctor if irritation persists.
After skin contact
In case of dust contact with skin, wash off with soap and water. Consult a doctor if skin irritation persists.

After swallowing
In case of swallowing, seek medical advice.

Cautions for the doctor
No specific antidote. Effect support therapy. Care should be effected according doctor’s evaluation with respect to the patient’s reactions.

Most important symptoms of exposure
This product is a non-hazardous polymer solid. Dust generated from polishing or grinding may cause eye or respiratory tract irritation.

5. FIREFIGHTING MEASURES

Suitable extinguishing agents
These products are not classified as flammable or combustible but will burn under fire conditions. Water spray jet, foam, dry powder, carbon dioxide

For safety reasons unsuitable extinguishing agents
Water with full jet.

Protective equipment for fire-fighting
Use self-contained respirator (breathing apparatus). Wear full protection suit.

6. ACCIDENTAL RELEASE MEASURES

Person-related safety precautions
Avoid build up of dust. Use breathing protection (Fine dust mask FFP) when exposed to dust. Use personal protective equipment (overalls, protective glasses and protective gloves).

Environmental Precautions
Report releases as required by local and national authorities.

Methods and Materials for Containment and Clean-up:
Pick up teeth and return to container for use. For dust from grinding or polishing products: Contain spills, sweep or gather spilled material in a manner that minimizes the generation of airborne dusts, and transfer to a suitable container for disposal.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Avoid generating dust. Avoid breathing dust. Use adequate ventilation for polishing or grinding operations. Wash hands thoroughly after polishing or grinding teeth. Use good housekeeping to minimize accumulation of dust.

Conditions for Safe Storage
No special storage required.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure information
None.

Technical devices
None.

Personnel protective equipment
None.

Respiratory Protection
No needed with normal usage. When product is grinded or polished, use localized aspiration of dusts and/or protective mask.

Skin protection
None particular precaution should be taken with normal usage.

Eye and visage protection
None particular precaution should be taken with normal usage. When the product is grinded or polished, use protective glasses.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state (at 20°C)</td>
<td>solid</td>
</tr>
<tr>
<td>Color</td>
<td>various</td>
</tr>
<tr>
<td>Odor</td>
<td>unscented</td>
</tr>
<tr>
<td>Specific weight (at 20°C)</td>
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</tr>
<tr>
<td>Solubility in water (at 20°C)</td>
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</tr>
<tr>
<td>PH (at 20°C)</td>
<td>--</td>
</tr>
<tr>
<td>Casting temperature</td>
<td>--</td>
</tr>
<tr>
<td>Boiling temperature</td>
<td>--</td>
</tr>
<tr>
<td>Auto ignition temperature</td>
<td>--</td>
</tr>
<tr>
<td>Inflammability temperature</td>
<td>--</td>
</tr>
<tr>
<td>Air deflagration limits</td>
<td>--</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Dangerous reactions
No dangerous reactions known.

Chemical Stability
Stable.

Conditions to Avoid
Stable in normal conditions.

Hazardous Decomposition Products
Decomposition may release oxides of carbon, methyl methacrylate, and irritating smoke and fumes.
Materials to avoid
None in particular.

Hazardous decomposition products
None when correctly utilized.

11. TOXICOLOGICAL INFORMATION

Sensitisation
Allergic reactions were reported among humans. The product contains small quantities of sensitising substances (methyl methacrylate). Intensive skin contact, especially with the dissolved product, can trigger an allergic reaction in persons previously sensitised.

Further information
The biocompatibility tests carried out on the teeth, in accordance with EN ISO 10993, regarding cytotoxicity, toxicity test, stimulate or intradermal reaction, acute systemic toxicity and delayed type, did not result in any negative effects, under the test conditions, on the cell materials used. The fines which appear during sharpening can lead to mechanical irritations of the skin, eyes, and mucous membranes. Skin and eye contact with the product should be avoided. The inhalation of product dusts should be avoided.

12. ECOLOGICAL INFORMATION

Degradation
The material is known to be stable in environment. Due to the law biodegradability the product should not reach water or ground.

Aquatic toxicity
Insoluble. No dangers for environment are known.

13. DISPOSAL CONSIDERATIONS

Recommendation
The waste is not dangerous and can be disposed together with household garbage. Disposal area must comply with the environment and national safety standard.

14. TRANSPORT INFORMATION

None.

15. REGULATORY INFORMATION

The product is subject to the regulations of the Medical Device Directive 93/42/EEC, as well as to the national Medical Device Act and the Chemicals Act.
16. OTHER INFORMATION

No further technical information

The present data sheet contains technical-scientific information processed at best of our knowledge. We recommend verifying national and regional regulations applicable to the specific utilize field as well as regulations relative hygienic and safety on work and environment worship.

All information contained in the present data sheet is correct and processed in good faith. However they do not involve any obligation, guarantee and patent concession.

The characteristics mentioned in the following document do not constitute contractual specifications.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)