

**Safety Data Sheet**

according to Regulation (EC) No 1907/2006

**PREMIOTEMP**

Revision date: 03/2015

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**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

| <b>Hazardous Components</b> | <b>C.A.S. #</b> | <b>EINECS #</b> | <b>Substance Classification</b> | <b>WT %</b> |
|-----------------------------|-----------------|-----------------|---------------------------------|-------------|
| Methyl methacrylate         | 000080-62-6     | 201-297-2       | Not Applicable                  | <1.5        |

**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.

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**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.

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**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.

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**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.

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**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.

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**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**

|                               |           |
|-------------------------------|-----------|
| Physical state (at 20°C)      | solid     |
| Color                         | various   |
| Odor                          | unscented |
| Specific weight (at 20°C)     | --        |
| Solubility in water (at 20°C) | insoluble |
| PH (at 20°C)                  | --        |
| Casting temperature           | --        |
| Boiling temperature           | --        |
| Auto ignition temperature     | --        |
| Inflammability temperature    | --        |
| Air deflagration limits       | --        |

**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.

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**Materials to avoid**

None in particular.

**Hazardous decomposition products**

None when correctly utilized.

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**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.

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**12. ECOLOGICAL INFORMATION****Degradation**

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

**Aquatic toxicity**

Insoluble. No dangers for environment are known.

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**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.

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**14. TRANSPORT INFORMATION**

None.

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**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.

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**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.)*