

Safety Data Sheet

Synthetic Polymer Teeth

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Synthetic Polymer Teeth

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.3. Details of the supplier of the safety data sheet

Company Name: VinciSmile Group LLC
Address: 16453 Old Valley Blvd
City, State, Zip Code: La Puente, CA, 91744, USA
Telephone: Tel: +1 626 283 5808
email address: marketing@vincismile.com
Website: www.vincismile.com

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Product classification

May cause sensitisation by skin contact.

2.2. Label elements

Hazard statements

The product presents no toxic hazard when used according to 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.

2.3. Other hazards

No risks worthy of mention. Please observe the information on the safety data sheet at all times.

SECTION 3: Composition/information on ingredients

3.1. Mixtures

Chemical characterization

Polymethylmethacrylate with high molecular weight Methylmethacrylate

Pigments: Iron oxide and Titanium dioxide

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

SECTION 4: First aid measures

4.1. Description of 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.

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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.

SECTION 5: Firefighting measures

5.1. Extinguishing media

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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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).

6.2. Environmental precautions

Report releases as required by local and national authorities.

6.3. Methods and material for containment and cleaning 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.

SECTION 7: Handling and storage

7.1. 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.

7.2. Conditions for safe storage, including any incompatibilities

No special storage required.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

None.

8.2. Exposure controls

None.

Respiratory protection

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

Eye protection

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

Skin protection

None particular precaution should be taken with normal usage.

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SECTION 9: Physical and chemical properties

9.1. Information on basic 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 | -- |

SECTION 10: Stability and reactivity

10.1. Conditions to avoid

Stable in normal conditions.

10.2. Incompatible materials

None

10.3. Hazardous decomposition products

Decomposition may release oxides of carbon, methyl methacrylate, and irritating smoke and fumes.

None when correctly utilized.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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.

Irritation and corrosivity

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 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.

SECTION 12: Ecological information

12.1. Toxicity

Insoluble. No dangers for environment are known.

12.2. Persistence and degradability

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

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

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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SECTION 14: Transport information

UN number: n.a.
class: n.a.
packaging group: n.a.
ocean harmful substances: n.a.
other relevant information: no hazardous good

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

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.

SECTION 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.