

SAFETY DATA SHEET

CHEMICAL SUBSTANCE / MIXTURE REGULATION (EC) No1907/2006 AS AMENDED BY REGULATION (EU) No 453/2010

SECTION 1: IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY

1.1. Product identifiers

| Product names | i-PLAST OR (powder) |
|-----------------|--|
| Chemical name | - · |
| Identified uses | Self curing acrylic resin for orthodontic appliances |

1.2. Details of the supplier of the safety data sheet

Company Address

Telephone Fax E-mail address

1.3. Emergency telephone number Emergency telephone number (Available only during office hours) +370 41 553 553 +370 41 553 551 dental@i-dental.lt

UAB "Medicinos linija"

Karaliaučiaus str. 29 LT-78374 Šiauliai, Lithuania

+370 41 553 553

SECTION 2: HAZARDS IDENTIFICATION

- 2.1. Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP] No significant hazard
- 2.2. Label elements Pictograms No pictograms Signal word No signal word

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1. Information on hazardous ingredients:

| Name | CĂS No | EC No | Hazard statement | Content, % |
|--------------------|---------|-----------|------------------|------------|
| Dibenzoyl peroxide | 94-36-0 | 202-327-6 | H241, H317, H319 | <1 |

SECTION 4: FIRST AID MEASURES

4.1. General advice

In doubt, consult a physician. Show this safety data sheet to the doctor in attendance.

4.2. If swallowed

Never give anything by mouth to an unconscious person. Take casualty to the hospital.

If the person is conscious rinse the mouth and spit the fluids out. **Do NOT induce vomiting**. Refer for medical attention if irritation symptoms persist.

4.3. In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Refer for medical attention if irritation symptoms persist.

4.4. If inhaled

Remove the casualty from the hazardous area and take him to the fresh air. If not breathing, give artificial respiration. Keep warm and at rest. Refer for immediate medical attention.

4.5. In case of skin contact

Take off contaminated clothing. Wash off with plenty of water. If symptoms (irritation) occur obtain medical attention. Wash contaminated clothing before reuse.

- 4.6. Most important symptoms and effects, both acute and delayed No data available.
- 4.7. Indication of any immediate medical attention and special treatment needed No data available.

SECTION 5: FIRE FIGHTING MEASURES

5.1. Extinguishing media

- Use extinguishing media appropriate to the surrounding fire conditions (foam and CO₂).
- 5.2. Unsuitable extinguishing media
- Direct jet of water.

- 5.3. Advice for fire fighters
 - Standard procedure for chemical fires.
- 5.4. **Special hazards arising from the substance or mixture** No data available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

- 6.1. **Personal precautions, protective equipment and emergency procedures** Use personal protective equipment. Ensure adequate ventilation.
- 6.2. Environmental precautions Do not let product enter drains.
- 6.3. **Methods and materials for containment and cleaning up** Use personal protective equipment when cleaning. Sweep up, transfer to suitable, labelled container for disposal and dispose. Clean spillage area thoroughly with plenty of water.
- 6.4. **Reference to other sections** For disposal see section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Avoid contact with eyes and skin. Use personal protective equipment. Keep tightly closed. Keep away from food, drinks and animal feed. Do not eat, drink or smoke when using this product.

- 7.2. Conditions for safe storage, including any incompatibilities Keep in cool, well ventilated place. Keep away from heat and direct sunlight. Storage temperature: Preferably not exceeding 25°C.
- 7.3. Specific end uses Dental use only.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Exposure limit values

| Substance | CAS No. | TWA 8 hr |
|--|---------|----------|
| Dibenzoyl peroxide | 94-36-0 | 5 mg/m³ |
| Dust (total inhalable dust) (respirable dust) | - | 10 mg/m³ |

8.2. Exposure controls

Provide adequate ventilation. Storage properly (p.7). Preventive medical check-ups should be arranged.

8.3. Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.4. Personal protective equipment

8.4.1. Eye/face protection

Wear eye / face protection equipment. Safety glasses with side-shields, conforming to EN 166.

8.4.2. Hand protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. For the permanent contact in work areas without heightened risk of injury (e.g. laboratory) gloves made of the following material are suitable: Polyvinyl alcohol or latex gloves. Warning: PVA is soluble in water! The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

8.4.3. Skin protection

Keep working clothes separately. Take off contaminated clothing immediately. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

8.4.4. **Respiratory protection**

Not necessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter P-S pr FFP-S).

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

| | Appearance | powder | |
|------|---|-----------------------------------|--|
| | Odour | faint ester like | |
| | Colour | clear | |
| 9.2. | 2. Important health, safety and environment information | | |
| | Melting point | >240 ⁰ C decomposition | |

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Stability
 - Stable under normal conditions
- 10.2. Conditions to avoid
 - Protect from heat and direct sunlight.
- 10.3. Materials to avoid No data available.
- 10.4. Hazard decomposition products Methyl methacrylate, carbon monoxide, carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Possible dangerous to health effects

No data available regarding specific product. Methyl methacrylate is in essential non-toxic, when absorbed into the body by any route. However for some few individuals it is a powerful skin sensitizer. Apart from this skin allergy, human cases of ill health caused by the product are of a low probability.

- 11.2. Germ cell mutagenicity
- No data available.

11.3. Carcinogenicity IARC: No components of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

- 11.4. Reproductive toxicity
- No data available.
- 11.5. Specific target organ toxicity single exposure

Inhalation: Unlikely to be hazardous by inhalation. Skin contact: Unlikely to cause skin irritation. Eye contact: Dust may cause irritation Ingestion: Low oral toxicity.

- 11.6. Specific target organ toxicity repeated exposure
- No data available. 11.7. Aspiration hazard
 - No data available.
- 11.8. Additional Information

None of effects are likely to occur in humans, provided exposure is maintained at or below occupational exposure limit.

11.9. Toxicity data Benzoyl peroxide: Acute oral rat: LD50 = > 5000 mg/kg. Methyl methacrylate: Acute oral rat: LD50 = 7872 mg/kg.

SECTION 12: ECOLOGICAL INFORMATION

- 12.1. Ecotoxicity
- 12.2. Mobility
- 12.3. Persistence and degradability
- 12.4. Bio accumulative potential
- 12.5. Results of PBT and vPvB assessment
- 12.6. Other adverse effects

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Disposal should be in accordance with local, state or national legislation. Offer surplus and non-recyclable solutions to a licensed disposal company. Contaminated packaging dispose of as unused product. Do not remove the information from package.

SECTION 14: TRANSPORT INFORMATION

14.1. The product is not classified as dangerous for carriage

SECTION 15: REGULATORY INFORMATION

- 15.1. This safety datasheet complies with the requirements of Regulation (EC) No 1907/2006 as amended by Regulation (EU) No 453/2010.
- 15.2. Other Regulations: EINECS: Components of mixture are on the European Inventory of Existing Commercial Chemical Substances.
- 15.3. This safety data sheet information is not a professional risk assessment.
- 15.4. Safety, health and environmental regulations/legislation specific for the substance or mixture No data available.
- 15.5. Chemical Safety Assessment No data available.
- 15.6. Health, safety and environmental information

No data available regarding specific product No data available No data available No data available No data available No data available

No data available.

SECTION 16: OTHER INFORMATION

- 16.1. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.
- 16.2. UAB "Medicinos linija" shall not be held liable for any damage resulting from handling or from contact with the above product.
- 16.3. The product should not be used for purposes other than specified in p.7.3 purposes.
- 16.4. User is responsible for the legal, regulatory compliance.
- 16.5. References to the changes that have been made in comparison with __-_ version: whole document.
- 16.6. Abbreviations and acronyms used in the safety data sheet:
 - 16.6.1. EC European Commission
 - 16.6.2. GHS Globally Harmonized System
 - 16.6.3. CLP Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
 - 16.6.4. CAS No Chemical Abstracts Service number
 - 16.6.5. EC No EINECS and ELINCS Number (see also EINECS and ELINCS)
 - 16.6.6. PBT Persistent, Bio accumulative and toxic substance
 - 16.6.7. VPvB Very Persistent and Very Bio accumulative
 - 16.6.8. ADR European Agreement concerning the International Carriage of Dangerous Goods by Road
 - 16.6.9. UN United Nations
 - 16.6.10. LC50 Lethal Concentration to 50 % of a test population
 - 16.6.11. LD50 Lethal Dose to 50% of a test population (Median Lethal Dose)
- 16.7. Key literature references and sources for data: <u>http://echa.europa.eu</u>.
- 16.8. List of relevant hazard statements, safety phrases and/or precautionary statements full text:
 - H241: Heating may cause a fire explosion
 - H317: May cause an allergic skin reaction
 - H319: Causes serious eye irritation
- 16.9. Training advice: How to properly handle chemical substances / mixtures employees must be trained in accordance with national requirements.