

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-FIX Plus (powder)
Chemical name	-
Identified uses	Resin modified glass ionomer luting cement

1.2. Details of the supplier of the safety data sheet

Company	UAB "Medicinos linija"
Address	Karaliaučiaus str. 29 LT-78374 Šiauliai, Lithuania
Telephone	+370 41 553 553
Fax	+370 41 553 551
E-mail address	dental@i-dental.lt

1.3. Emergency telephone number

Emergency telephone number (Available only during office hours)	+370 41 553 553
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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 ingredients:

Name	CAS No	EC No	Hazard statement	Content, %
Glass Powder	65997-18-4	-	-	80-100

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

Irritating to respiratory system. Inhalation may cause coughing, tightness of the chest and irritation of the respiratory system.

Irritating to eyes.

Irritating to skin.

Ingestion may cause nausea and vomiting.

4.7. Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5: FIRE FIGHTING MEASURES

- 5.1. **Extinguishing media**
Carbon oxides.
- 5.2. **Advice for fire fighters**
Standard procedure for chemical fires.
- 5.3. **Special hazards arising from the substance or mixture**
Burning produces irritating, toxic and obnoxious fumes.

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**
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- 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: PVC gloves 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 A).

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

- 9.1. **General information**

Appearance	powder
Odour	odourless
Colour	white
- 9.2. **Important health, safety and environment information**
No data available

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**
No data available.

SECTION 11: TOXICOLOGICAL INFORMATION

- 11.1. **Possible dangerous to health effects**
No data available regarding specific product.
- 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**
No data available.
- 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**
No data available.

SECTION 12: ECOLOGICAL INFORMATION

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|---|-------------------|
| 12.1. Ecotoxicity | No data available |
| 12.2. Mobility | No data available |
| 12.3. Persistence and degradability | No data available |
| 12.4. Bio accumulative potential | No data available |
| 12.5. Results of PBT and vPvB assessment | No data available |
| 12.6. Other adverse effects | No data available |

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.

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: <http://echa.europa.eu>.

16.8. List of relevant hazard statements, safety phrases and/or precautionary statements full text: None

16.9. Training advice: How to properly handle chemical substances / mixtures employees must be trained in accordance with national requirements.