

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/UNDERTAKING

1.1. Product identifier

Product name **i-FIX Plus (powder)**
Chemical name -

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

Relevant identified uses Resin modified glass ionomer luting cement

1.3. Details of the supplier of the safety data sheet

Company UAB "Medicinos linija"
Address Aviacijos str. 28
LT-77103 Siauliai, Lithuania
Telephone +370 41 553 553
E-mail address info@i-dental.lt

1.4. Emergency telephone number

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

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

2.1.1. Classification according to Regulation (EC) No 1272/2008 [CLP]

No significant hazard

2.2. Label elements

2.2.1. Labelling according to Regulation (EC) No 1272/2008 [CLP]

Pictograms No pictograms

Signal word No signal word

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1. Information on ingredients:

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

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

4.1.1. General advice

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

4.1.2. 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.

4.1.3. 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.

4.1.4. 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.

4.1.5. 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.

4.2. 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.

4.3. **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. **Special hazards arising from the substance or mixture**

Burning produces irritating, toxic and obnoxious fumes.

5.3. **Advice for fire fighters**

Standard procedure for chemical fires.

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. **Control parameters**

8.1.1. **Exposure limit values**

No exposure guidelines have been established for mixture. ACGIH, NIOSH and OSHA have not developed exposure limits for this product.

8.2. **Exposure controls**

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

8.2.1. **Appropriate engineering controls**

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

8.2.2. **Personal protective equipment**

8.2.2.1. **Eye/face protection**

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

8.2.2.2. **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.

8.2.2.3. **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.

8.2.2.4. **Respiratory protection**

Not necessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).

8.2.3. **Environmental exposure controls**

Do not let enter the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	white powder
Odour	odourless

SECTION 10: STABILITY AND REACTIVITY**10.1. Reactivity**

No data available.

10.2. Chemical stability

Stable under recommended storage conditions

10.3. Possibility of hazardous reactions

No data available

10.4. Conditions to avoid

Protect from heat and direct sunlight.

10.5. Incompatible materials

No data available.

10.6. Hazard decomposition products

No data available.

SECTION 11: TOXICOLOGICAL INFORMATION**11.1. Information on toxicological effects****11.1.1. Acute toxicity**

No data available.

11.1.2. Skin corrosion/irritation

No data available.

11.1.3. Serious eye damage/eye irritation

No data available.

11.1.4. Respiratory or skin sensitization

No data available.

11.1.5. Germ cell mutagenicity

No data available.

11.1.6. 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.

11.1.7. Reproductive toxicity

No data available.

11.1.8. Specific target organ toxicity - single exposure

No data available.

11.1.9. Specific target organ toxicity - repeated exposure

No data available.

11.1.10. Aspiration hazard

No data available.

11.1.11. Additional Information

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

SECTION 12: ECOLOGICAL INFORMATION**12.1. Ecotoxicity**

No data available

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

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. AIR TRANSPORT (IATA)**

Not regulated as a hazardous material.

14.2. LAND TRANSPORT (ADR/RID)

Not regulated as a hazardous material.

14.3. MARINE TRANSPORT (IMDG)

Not regulated as a hazardous material.

SECTION 15: REGULATORY INFORMATION

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

This safety datasheet complies with the requirements of Regulation (EC) No 1907/2006 as amended by Regulation (EU) No 453/2010.

Other Regulations: EINECS: Components of mixture are on the European Inventory of Existing Commercial Chemical Substances.

This safety data sheet information is not a professional risk assessment.

15.2. Chemical Safety Assessment

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 2015-07-01 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.