

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-FIL (powder)**
 Chemical name -

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

Relevant identified uses Glass ionomer filling 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]

Eye Irrit. 2

2.2. Label elements

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

Pictograms



Signal word **Warning**

Hazard statements

H319: Causes serious eye irritation

Precautionary statements (prevention)

P264: Wash thoroughly after handling

P280: Wear protective gloves/protective clothing/eye protection/face protection

Precautionary statements (response)

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313: If eye irritation persists: Get medical advice/attention.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1. Information on ingredients:

Name	CAS No	EC No	Index No	Hazard statement	Content, %
L(+) Tartaric Acid	87-69-4	201-766-0	-	H315, H319, H335	1-10

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

No data available.

4.3. 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.

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 28°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	powder
Odour	odourless
Colour	not required

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

No data available.

10.2. Chemical stability

Stable under recommended 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.
- 15.3. **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 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:
H315: Causes skin irritation
H319: Causes serious eye irritation
H335: May cause respiratory irritation
P261: Avoid breathing dust/fume/gas/mist/vapours/spray
P264 - Wash thoroughly after handling
P280: Wear protective gloves/protective clothing/eye protection/face protection
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P302+P352: IF ON SKIN: Wash with plenty of water
P332+P313: If skin irritation occurs: Get medical advice/attention
P362+P364: Take off contaminated clothing and wash it before reuse
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing
P312: Call a POISON CENTER or doctor if you feel unwell
- 16.9. Training advice: How to properly handle chemical substances / mixtures employees must be trained in accordance with national requirements.