

SAFETY DATA SHEET

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

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

- 1.1. Product identifiers**
 Product name **i-FLOR**
 Identified uses Sustained release fluoride gel
- 1.2. Details of the supplier of the safety data sheet**
 Company JSC "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 +370 41 553 553
 (Available only during office hours)

SECTION 2: HAZARDS IDENTIFICATION

- 2.1. Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]**
 Acute Tox. 3, oral
 Skin Irr. 2
 Eye Irrit. 2

- 2.1.1. Label elements**
Pictogram



Signal word **Danger**

Hazard statement

H301: Toxic if swallowed
 H315: Causes skin irritation
 H319: Causes serious eye irritation

Precaution statement (prevention)

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

Precaution statement (response)

P301+P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
 P321: Specific treatment: Give one or two glasses of water to drink
 P337+P313: If eye irritation persists: Get medical advice/attention

Other hazards

EUH032: Contact with acids liberates very toxic gas

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

- 3.1. Hazardous components of the mixture:

Name	CAS No	EC No	Index No	Hazard statement	Content, %
Sodium Fluoride	7681-49-4	231-667-8	009-004-00-7	H301, H315, H319	<0.5

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 inhaled**
 Remove the casualty from the hazardous area and take him to the fresh air. Half-upright position. If not breathing, give artificial respiration. Consult a physician.
- 4.3. In case of skin contact**
 Take off contaminated clothing. Wash off with soap and plenty of water. Skin exposures can be treated with a 2.5% calcium gluconate gel. Consult a physician.
- 4.4. 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.
- 4.5. If swallowed**

Never give anything by mouth to an unconscious person. Take casualty to the hospital.
Rinse mouth. Induce vomiting (ONLY IN CONSCIOUS PERSONS!). Give one or two glasses of water to drink.
Refer for medical attention.

4.6. Most important symptoms and effects, both acute and delayed

Inhalation: Cough. Sore throat.

Skin: Redness.

Eyes: Redness. Pain.

Ingestion: Abdominal pain. Burning sensation. Convulsions. Drowsiness. Cough. Diarrhoea. Sore throat.

Vomiting: Unconsciousness.

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

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

No data available.

SECTION 5: FIRE FIGHTING MEASURES

5.1. Extinguishing media

Suitable all extinguishing media.

5.2. Advice for fire fighters

Wear self contained breathing apparatus for fire fighting. Not combustible. Contact with acids liberates toxic hydrogen fluoride gas. Wear self contained breathing apparatus for fire fighting if necessary.

5.3. Special hazards arising from the substance or mixture

Contact with acids liberates very toxic gas.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid vapour formation. Do not breathe vapours, mist or gas. NO open flames, NO contact with hot surfaces.

6.2. Environmental precautions

Do NOT let this chemical enter the environment. Sweep spilled substance into covered containers. Carefully collect remainder. Then store and dispose of according to local regulations.

6.3. Methods and materials for containment and cleaning up

Sweep spilled substance into covered containers. Carefully collect remainder. Then store and dispose of according to local regulations

6.4. Reference to other sections

For disposal see section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Use personal protective equipment. Avoid vapour formation. Do not breathe vapours, mist or gas. Closed system, ventilation. Wash hands thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Cool. Separated from food and feedstuffs and incompatible materials. On contact with hot surfaces or flames this substance decomposes forming toxic and corrosive fumes . Reacts with acids to produce toxic and corrosive fumes.

7.3. Specific end uses

Chemical analytics, biochemistry.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Exposure limit values

TLV: (as fluoride) 2.5 mg/m³ as TWA; A4 (not classifiable as a human carcinogen); BEI issued; (ACGIH 2003).

MAK: (as F) (Inhalable fraction) 1 mg/m³.

8.2. Exposure controls

Install ventilation to prevent vapour formatting.

Handling properly (p.7).

Contain no substances with occupational exposure limit values.

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. Do not smoke when handle.

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 chemical resistance (PVC, neoprene, rubber) 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. 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

Impervious clothing. 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

Does not dust. If you need to protect the airways use respirators, that have been tested and approved by the relevant governmental standards, such as CEN (EU) or NIOSH (USA).

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. General information

Appearance	Gel
Colour	Clear colourless
Odour	Odourless

9.2. Important health, safety and environment information

Flash point	No data available
Specific gravity	No data available
Refractive index	No data available
Viscosity at 25 ^o C	No data available
Solubility	No data available

SECTION 10: STABILITY AND REACTIVITY

10.1. Stability

Stable under normal temperature and pressure.

10.2. Conditions to avoid

Light, heat, humidity.

On contact with hot surfaces or flames this substance decomposes forming toxic and corrosive fumes. Reacts with acids to produce toxic and corrosive fumes.

10.3. Materials to avoid

Acids, silicates.

10.4. Hazard decomposition products

Contact with acids liberates toxic hydrogen fluoride gas.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Possible dangerous to health effects

The substance can be absorbed into the body by inhalation of its aerosol and by ingestion.

Inhalation. May be harmful if inhaled vapour. May cause respiratory tract irritation.

Ingestion. May be harmful if swallowed.

Skin. May be harmful if absorbed through skin. May cause skin irritation.

Eyes. Causes serious eye irritation.

Detailed: p.4.6.

11.2. Signs and Symptoms of Exposure

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Detailed in p.4.6.

11.3. Toxicity

LD50 oral rat: 52 mg/kg.

11.4. Skin corrosion/irritation

No data available

11.5. Serious eye damage/eye irritation

No data available

11.6. Respiratory or skin sensitization

No data available.

11.7. Germ cell mutagenicity

No data available

11.8. Carcinogenicity

IARC Carcinogen category: not classifiable as a human carcinogen.

11.9. Specific target organ toxicity - single exposure

The substance is irritating to the eyes, the skin and the respiratory tract. Exposure when ingested could cause hypocalcaemia and hypokalaemia, resulting in central nervous system and cardiac disorders.

11.10. Specific target organ toxicity - repeated exposure

The substance may have effects on the bones and teeth (fluorosis).

11.11. Aspiration hazard

No data available.

11.12. Additional Information

No data available.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Ecotoxicity	LC50 fish (96 hours), minimum 51mg/l, maximum 830mg/l
12.2. Mobility	No data available
12.3. Persistence and degradability	Accumulated in vegetable leaves
12.4. Bio accumulative potential	No data available

12.5. **Results of PBT and vPvB assessment**

No data available

12.6. **Other adverse effects**

Hazardous for aquatic organisms

SECTION 13: DISPOSAL CONSIDERATIONS13.1. **Waste treatment methods**

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. Manage waste as required by regulatory requirements. Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

14.1. Not a subjects for transport regulation

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. Abbreviations and acronyms used in the safety data sheet:

16.5.1. EC – European Commission

16.5.2. EU – European Union

16.5.3. GHS – Globally Harmonized System

16.5.4. CLP – Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

16.5.5. CAS No – Chemical Abstracts Service number

16.5.6. EC No – EINECS and ELINCS Number (see also EINECS and ELINCS)

16.5.7. EINECS – European Inventory of Existing Commercial Substances

16.5.8. IARC – International Agency for Research on Cancer

16.5.9. PBT - Persistent, Bio accumulative and toxic substance

16.5.10. vPvB – Very Persistent and Very Bio accumulative

16.6. Key literature references and sources for data: <http://echa.europa.eu>.

16.7. List of relevant hazard statements, safety phrases and/or precautionary statements full text:

Signal word Danger

H301: Toxic if swallowed

H315: Causes skin irritation

H319: Causes serious eye irritation

P264: Wash hands thoroughly after handling

P270: Do not eat, drink or smoke when using this product

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

P301+P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician

P330: Rinse mouth

P302+P352: IF ON SKIN: Wash with plenty of soap and water

P332+P313: If skin irritation occurs: Get medical advice/attention

P362: Take off contaminated clothing and wash before reuse

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

P321: Specific treatment (see SECTION 4)

P405: Store locked up

P501: Dispose of contents/container to as required by regulatory requirements

EUH032: Contact with acids liberates very toxic gas

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