

**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-SMILE**  
Chemical name -  
Identified uses Tooth whitening gel

**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](mailto: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]**

Skin Corr. 1B  
Acute Tox. 3, oral  
Skin Irr. 2  
Eye Irrit. 2

**2.1.1. Label elements****Pictograms**

**Signal word** **Danger**

**Hazard statements**

H314: Causes severe skin burns and eye damage  
H272: May intensify fire; oxidizer  
H301: Toxic if swallowed  
H315: Causes skin irritation  
H319: Causes serious eye irritation  
EUH032: Contact with acids liberates very toxic gas

**Precaution statements (prevention)**

P264: Wash hands thoroughly after handling  
P280: Wear protective gloves/ eye protection/ face protection  
P270: Do not eat, drink or smoke when using this product

**Precaution statements (response)**

P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting  
P301+P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician  
P321: Specific treatment: Give one or two glasses of water to drink  
P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower  
P362: Take off contaminated clothing and wash before reuse  
P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing  
P310: Immediately call a POISON CENTER or doctor/physician  
P321: Specific treatment (see section 4 on this label).  
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

**Precaution statements (storage)**

P405: Store locked up  
P403+P233: Store in a well-ventilated place. Keep container tightly closed

**Precaution statements (disposal)**

P501: Dispose of contents/ container to an approved waste disposal company

**SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS**

## 3.1. Information on ingredients:

<b>Name</b>	<b>CAS No</b>	<b>EC No</b>	<b>Hazard statement</b>	<b>Content, %</b>
Carbamide Peroxide	124-43-6	204-701-4	H314, H272	10-16
Sodium Fluoride	7681-49-4	231-667-8	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 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. Subsequently, have the casualty drink 1 - 2 glasses of water immediately. **Do NOT induce vomiting.** During spontaneous vomiting hold the head of the casualty low with the body in a prone position in order to avoid the penetration of vomit into the air tube. Refer for immediate medical attention.

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 immediate medical attention.

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**

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**

Use water spray.

5.2. **Advice for fire fighters**

Standard procedure for chemical fires.

5.3. **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. Avoid breathing vapours, mist or gas. 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. Remove mechanically and with care (small spill: wipe up with cloth, soap and water; large spill: absorb with inert, damp non-combustible material, then flush area with water). Place in container for disposal according to local / national regulations.

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 away from food, drinks and animal feed. Do not eat or drink 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 - away from strong bases, metals. Excess heat, exposure to moist air or water. Incompatible materials: Strong caustics, most metals.

7.3. **Specific end uses**

Tooth whitening gel.

**SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION**8.1. **Exposure limit values**

Contains no substances with occupational exposure limit values.

8.2. **Exposure controls**

Provide adequate ventilation to ensure that the defined occupational exposure limit is not exceeded. 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. 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**

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

viscous gel

Odour

orange, apple (according to product specification)

Colour

transparent

### 9.2. **Important health, safety and environment information**

Solubility in water

partially soluble

Flash point

no data available

## SECTION 10: STABILITY AND REACTIVITY

### 10.1. **Stability**

Stable under normal temperature and pressure

### 10.2. **Conditions to avoid**

Avoid strong bases, metals. Excess heat, exposure to moist air or water.

### 10.3. **Materials to avoid**

Strong caustics, most metals.

### 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. **Inhalation**

No data available.

### 11.3. **Skin corrosion/irritation**

Causes severe skin burns and irritation.

### 11.4. **Serious eye damage/eye irritation**

Causes irritation and eye damage.

### 11.5. **Respiratory or skin sensitization**

No data available.

### 11.6. **Ingestion**

Harmful if swallowed.

### 11.7. **Germ cell mutagenicity**

No data available.

### 11.8. **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.

### 11.9. **Reproductive toxicity**

No data available.

### 11.10. **Specific target organ toxicity - single exposure**

No data available.

### 11.11. **Specific target organ toxicity - repeated exposure**

No data available.

### 11.12. **Aspiration hazard**

No data available.

### 11.13. **Additional Information**

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

limit.

#### 11.14. Toxicity data

Carbamide Peroxide: Acute oral toxicity: LD50 rat: > 2.000 mg/kg; Test substance: carbamide peroxide

### SECTION 12: ECOLOGICAL INFORMATION

12.1. Ecotoxicity	No data available regarding specific product
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. Abbreviations and acronyms used in the safety data sheet:
- 16.5.1. EC – European Commission
  - 16.5.2. GHS – Globally Harmonized System
  - 16.5.3. CLP – Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
  - 16.5.4. CAS No – Chemical Abstracts Service number
  - 16.5.5. EC No – EINECS and ELINCS Number (see also EINECS and ELINCS)
  - 16.5.6. PBT - Persistent, Bio accumulative and toxic substance
  - 16.5.7. vPvB – Very Persistent and Very Bio accumulative
  - 16.5.8. LD50 – Lethal Dose to 50% of a test population (Median Lethal Dose)
- 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  |
|-------------|---|
|             | H314: Causes severe skin burns and eye damage                                 |
|             | H272: May intensify fire; oxidizer  |
|             | H301: Toxic if swallowed  |
|             | H315: Causes skin irritation  |
|             | H319: Causes serious eye irritation   |
|             | EUH032: Contact with acids liberates very toxic gas                           |
|             | P264: Wash hands thoroughly after handling                                    |
|             | P280: Wear protective gloves/ eye protection/ face protection                 |
|             | P270: Do not eat, drink or smoke when using this product                      |
|             | P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting             |
|             | P301+P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician |
|             | P321: Specific treatment: Give one or two glasses of water to drink           |

P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower

P362: Take off contaminated clothing and wash before reuse

P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

P310: Immediately call a POISON CENTER or doctor/physician

P321: Specific treatment (see section 4 on this label).

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

P405: Store locked up

P403+P233: Store in a well-ventilated place. Keep container tightly closed

P501: Dispose of contents/ container to an approved waste disposal company

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