

# 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-SMILE  
Chemical name -

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

Relevant identified uses Chemical analytics, biochemistry

#### 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](mailto: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]

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

#### 2.2. Label elements

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

###### 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  
 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:

Name	CAS No	EC No	Index No	Hazard statement	Content, %
Carbamide peroxide	124-43-6	204-701-4	-	H314, H272	10-16
Sodium fluoride	7681-49-4	231-667-8	009-004-00-7	H301, H315, H319	<0.5

**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 immediate medical attention.

## 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.** 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 medical attention.

## 4.2. 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.

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

No data available.

## 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. 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 (e.g. with clean polyethylene plastic shovel). Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and 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**  
Chemical analytics, biochemistry.

## SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

- 8.1. **Control parameters**
- 8.1.1. **Exposure limit values**  
Contains no substances with occupational 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, including appropriate local extraction, to ensure that the defined occupational exposure limit is not exceeded. 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. 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**  
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).
- 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          | transparent viscous gel                            |
| Odour               | orange, apple (according to product specification) |
| pH                  | 5-7  |
| Solubility in water | partially soluble                                  |
| Flash point         | no data available                                  |

## SECTION 10: STABILITY AND REACTIVITY

- 10.1. **Reactivity**  
No data available.
- 10.2. **Chemical stability**  
Stable under normal temperature and pressure
- 10.3. **Possibility of hazardous reactions**  
No data available.
- 10.4. **Conditions to avoid**  
Avoid strong bases, metals. Excess heat, exposure to moist air or water.
- 10.5. **Incompatible materials**  
Strong caustics, most metals.
- 10.6. **Hazard decomposition products**  
No data available.

## SECTION 11: TOXICOLOGICAL INFORMATION

- 11.1. **Information on toxicological effects**
- 11.1.1. **Acute toxicity**  
Carbamide peroxide oral rat LD50 >2000 mg/kg bw
- 11.1.2. **Skin corrosion/irritation**  
May cause skin irritation.
- 11.1.3. **Serious eye damage/eye irritation**  
May cause eye damage.
- 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**  
No data available.

## SECTION 12: ECOLOGICAL INFORMATION

- |   |  |
|---|--|
| 12.1. <b>Ecotoxicity</b>                        | No data available regarding specific product |
| 12.2. <b>Persistence and degradability</b>      | No data available                            |
| 12.3. <b>Bioaccumulative potential</b>          | No data available                            |
| 12.4. <b>Mobility in soil</b>                   | No data available                            |
| 12.5. <b>Results of PBT and vPvB assessment</b> | No data available                            |
| 12.6. <b>Other adverse effects</b>              | 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:

**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

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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

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