

## 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-CAL                   |
| Chemical name   | -                       |
| Identified uses | Calcium hydroxide paste |

##### 1.2. Details of the supplier of the safety data sheet

|                |  |
|----------------|--|
| Company        | UAB "Medicinos linija"                                     |
| Address        | Karaliaučiaus str. 29<br>LT-78374 Šiauliai, Lithuania      |
| Telephone      | +370 41 553 553  |
| Fax            | +370 41 553 551  |
| E-mail address | <a href="mailto:dental@i-dental.lt">dental@i-dental.lt</a> |

##### 1.3. Emergency telephone number

|  |                 |
|--|-----------------|
| Emergency telephone number<br>(Available only during office hours) | +370 41 553 553 |
|--|-----------------|

#### SECTION 2: HAZARDS IDENTIFICATION

##### 2.1. Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]

Skin Irrit. 2  
Eye Dam. 1

##### 2.1.1. Label elements

###### Pictograms



Signal word **Danger**

###### Hazard statements

H315: Causes skin irritation  
H318: Causes serious eye damage

###### Precaution statements (prevention)

P264: Wash hands thoroughly after handling  
P280: Wear protective gloves / protective clothing / eye protection / face protection  
P260: Do not breathe dust/fume/gas/mist/vapours/spray

###### Precaution statements (response)

P302+P352: IF ON SKIN: Wash with plenty of soap and water  
P321: Specific treatment (see SECTION 4 on this label)  
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  
P310: Immediately call a POISON CENTER or doctor/physician

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

##### 3.1. Information on ingredients:

| Name              | CAS No    | EC No     | Hazard statement | Content, % |
|-------------------|-----------|-----------|------------------|------------|
| Calcium hydroxide | 1305-62-0 | 215-137-3 | H315, H318       | 40-60      |

#### 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 2 large 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 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 mild soap and plenty of water. If symptoms (irritation or blistering) 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 suitable media for chemical fires.
- 5.2. **Advice for fire fighters**  
Standard procedure for chemical fires.
- 5.3. **Special hazards arising from the substance or mixture**  
Oxides of phosphorus.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

- 6.1. **Personal precautions, protective equipment and emergency procedures**  
Use personal protective equipment. Avoid contact with skin and eye. 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. Soak up with inert absorbent material and dispose. Keep in suitable, closed containers for disposal.
- 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 temperature: Preferably not exceeding 28°C.
- 7.3. **Specific end uses**  
Dental use only.

## SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

- 8.1. **Exposure limit values**  
Occupational Exposure limits

| SUBSTANCE              | CAS No.   | OSHA PEL            | NIOSH REL           |
|------------------------|-----------|---------------------|---------------------|
| Calcium hydroxide dust | 1305-62-0 | 5 mg/m <sup>3</sup> | 5 mg/m <sup>3</sup> |

- 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.
- 8.3. **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 paste |
| Odour      | specific      |
| Colour     | white         |

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

|               |                   |
|---------------|-------------------|
| pH            | >9                |
| Boiling point | no data available |
| Flash point   | no data available |

## SECTION 10: STABILITY AND REACTIVITY

### 10.1. **Stability**

Stable under normal temperature and pressure

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

No data available.

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

No data available.

### 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 skin irritation.

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

Causes serious eye damage.

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

May cause allergic skin reactions.

### 11.6. **Ingestion**

No data available.

### 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**

Calcium hydroxide: Acute toxicity LD50 per os, brown rat (mg/kg): 7340 mg/kg.

## SECTION 12: ECOLOGICAL INFORMATION

|   |  |
|---|--|
| 12.1. <b>Ecotoxicity</b>                        | No data available regarding specific product |
| 12.2. <b>Mobility</b>                           | No data available                            |
| 12.3. <b>Persistence and degradability</b>      | No data available                            |
| 12.4. <b>Bio accumulative potential</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 packagings 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. References to the changes that have been made in comparison with \_ 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**

H315: Causes skin irritation

H318: Causes serious eye damage

P264: Wash hands thoroughly after handling

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

P260: Do not breathe dust/fume/gas/mist/vapours/spray

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

P321: Specific treatment (see SECTION 4 on this label)

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

P310: Immediately call a POISON CENTER or doctor/physician

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