

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-EDTA
Chemical name	-
Identified uses	Root canal preparation 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

1.3. Emergency telephone number

Emergency telephone number (Available only during office hours)	+370 41 553 553
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SECTION 2: HAZARDS IDENTIFICATION

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

Acute Tox. 4
Skin Corr. 1B

2.1.1. Label elements

Pictograms



Signal word **Danger**

Hazard statements

H332: Harmful if inhaled
H314: Causes severe skin burns and eye damage

Precaution statements (prevention)

P264: Wash hands thoroughly after handling
P280: Wear protective gloves/ eye protection/ face protection

Precaution 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
P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting
P302+P352: IF ON SKIN: Wash with plenty of soap and water
P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower
P363: Wash contaminated clothing before reuse
P321: Specific treatment (see section 4 on this label)
P310: Immediately call a POISON CENTER or doctor/physician
P312: Call a POISON CENTER or doctor/physician if you feel unwell

Precaution statements (storage)

P405: Store locked up

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	Hazard statement	Content, %
Dihydrogenethylenediaminetetraacetic acid disodium salt	6381-92-6	-	H332	15
Carbamide Peroxide	124-43-6	204-701-4	H314	>10

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 medical attention immediately.
- 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, alcohol-resistant foam, dry chemical powder.
- 5.2. **Advice for fire fighters**
Unsuitable extinguishing media: carbon dioxide. Do not use a heavy water stream. Standard procedure for chemical fires.
- 5.3. **Special hazards arising from the substance or mixture**
Under fire conditions, hazardous fumes will be present.

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 temperature: Preferably not exceeding 28°C. Storage - away from: strong bases, strong acids.
- 7.3. **Specific end uses**
Dental use only.

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, 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 gel
Odour	odourless
Colour	white

9.2. Important health, safety and environment information

pH	5-7
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

Extremely high or low temperatures. Direct sunlight.

10.3. Materials to avoid

Strong acids. Oxidizing agent. Strong bases.

10.4. Hazard decomposition products

Fumes. May liberate toxic gases.

SECTION 11: TOXICOLOGICAL INFORMATION**11.1. Possible dangerous to health effects**

No data available regarding specific product.

11.2. Inhalation

Harmful if inhaled.

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 respiratory irritation.

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

Dihydrogenethylenediaminetetraacetic acid disodium salt: Inhalation: LOAEC:30 mg/m³ air; rat (OECD 412)
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. 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 |
|--------------------|---|
| | H332: Harmful if inhaled |
| | H315: Causes skin irritation |
| | H318: Causes serious eye damage |
| | H335: May cause respiratory irritation |
| | P261: Avoid breathing dust, fume, gas, mist, vapours, spray |
| | P262: Do not get in eyes, on skin, or on clothing |
| | P271: Use only outdoors or in a well-ventilated area |
| | P280: Wear protective gloves/ eye protection/ face protection |
| | P304 + P340+P312: Remove to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor if you feel unwell |
| | P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing |

P304+P341: IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing

P309+P311: IF exposed or if you feel unwell: Call a POISON CENTER or doctor/ physician

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.