

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-ENDO (liquid) |
| Chemical name | - |
| Identified uses | Root canal filling material |
- 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 |
|--|-----------------|

SECTION 2: HAZARDS IDENTIFICATION

- 2.1. Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]**
- Skin Sens.1
 - Eye Irrit.2
 - Acute Tox.4
 - Skin Irrit.2
- 2.2. Label elements**



Pictograms

Signal word **Warning**

Hazard statement

H317: May cause an allergic skin reaction
H319: Causes serious eye irritation
H315: Causes skin irritation
H302: Harmful if swallowed
EUH208: Contains eugenol. May produce an allergic reaction

Precautionary statement (prevention)

P261: Avoid breathing dust/fume/gas/mist/vapours/spray
P264: Wash hands thoroughly after handling
P272: Contaminated work clothing should not be allowed out of the workplace
P280: Wear protective gloves/protective clothing/eye protection/face protection

Precautionary statement (response)

P301+P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P330: IF SWALLOWED: rinse mouth. Do NOT induce vomiting
P302+P352: IF ON SKIN: Wash with plenty of soap and water
P333+P313: If skin irritation or rash occurs: Get medical advice/attention
P321: Specific treatment: rinse with plenty of water
P332+P313: If skin irritation occurs: Get medical advice/attention
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
P362: Take off contaminated clothing and wash before reuse
P363: Wash contaminated clothing before reuse
P310: Immediately call a POISON CENTRE or doctor/physician

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

- 3.1. Information on ingredients:

Name	CAS No	EC No	Hazard statement	Content, %
Eugenol	97-53-0	202-589-1	H317, H319, H315, H302, EUH208	99-100

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 glass of water in small sips 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) 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, water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
- 5.2. **Advice for fire fighters**
Standard procedure for chemical fires.
- 5.3. **Special hazards arising from the substance or mixture**
Carbon oxides.

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. Wipe small spill with absorbent paper cloth. Large spillage should be handled with inert non-combustible absorbent material (e.g. sand, sawdust). Collect spilled material in appropriate container for disposal. Dispose of as hazardous waste. 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 tightly closed. Keep away from food, drinks and animal feed. Do not eat, drink or smoke 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. Do not storage with strongly oxidizing substances.
- 7.3. **Specific end uses**
Dental use only.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

- 8.1. **Exposure limit values**
No exposure guidelines have been established. ACGIH, NIOSH and OSHA have not developed exposure limits for this product.
- 8.2. **Exposure controls**
Provide adequate ventilation to prevent vapour formation. 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. For the permanent contact in work areas without heightened risk of injury (e.g. laboratory) gloves made of the following material are suitable: PVC, neoprene, rubber gloves. 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

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	oily liquid
Odour	colourless to yellow
Colour	clove – like, spicy, pungent odour

9.2. Important health, safety and environment information

Concentration	99.5%
Flash point	> 98°C
Specific gravity	1.064 – 1.080 (d.25/25)
Refractive index	1.535 – 1.661
Viscosity at 25°C	No data available
Solubility	soluble in alcohol

SECTION 10: STABILITY AND REACTIVITY**10.1. Stability**

Stable under normal conditions

10.2. Conditions to avoid

Protect from heat and direct sunlight.

10.3. Materials to avoid

Strong oxidizing agents.

10.4. Hazard decomposition products

In combustion emits carbon monoxides and organic composites.

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

No data available regarding specific product.

11.2. Inhalation

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

11.3. Skin corrosion/irritation

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

11.4. Serious eye damage/eye irritation

Causes serious eye irritation.

11.5. Respiratory or skin sensitization

May cause allergic skin reactions.

11.6. Ingestion

May be 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

No data available.

11.14. Toxicity data

LD50 Oral - rat - 1.930 mg/kg.

Remarks: Behavioural: Altered sleep time (including change in righting reflex). Behavioural: Coma. Lungs, Thorax, or Respiration: Dyspnea

SECTION 12: ECOLOGICAL INFORMATION**12.1. Ecotoxicity**

LC50 - Oncorhynchus mykiss (rainbow trout) - 60,8 mg/l - 96 h

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 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:

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