

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-SEAL LC**
Chemical name -

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

Relevant identified uses Dental use only

1.3. Details of the supplier of the safety data sheet

Company UAB "Medicinos linija"
Address Karaliaucius str. 29
LT-78348 Siauliai, Lithuania
Telephone +370 41 553 553
E-mail address 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]**

Acute Tox. 4
Skin Irrit. 2
Skin Sens. 1
Eye Irrit. 2
STOT SE 3

2.2. Label elements**2.2.1. Labelling according to Regulation (EC) No 1272/2008 [CLP]****Pictograms**

Signal word **Warning**

Hazard statement

H302: Harmful if swallowed.
H315: Causes skin irritation.
H317: May cause an allergic skin reaction.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.

Precautionary statement (prevention)

P261: Avoid breathing vapours.
P264: Wash hands thoroughly after handling.
P270: Do not eat, drink or smoke when using this product.
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/ doctor if you feel unwell.
P330: Rinse mouth.
P302+P352: IF ON SKIN: Wash with plenty of water.
P321: Specific treatment: rinse with plenty of water.
P333+P313: If skin irritation or rash 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.
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P362+P364: Take off contaminated clothing and wash before reuse.

Precautionary statement (disposal)

P501: Dispose of contents/container to as required by national regulatory requirements.

2.3. Other hazards

Not applicable.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS**3.1. Substances:**

Name	CAS No	EC No	Index No	Hazard statement	Content, %
4-Methoxyphenol	150-76-5	205-769-8	604-044-00-7	Acute Tox. 4, H302; Skin Sens. 1, H317; Eye Irrit. 2, H319	<1

3.2. Mixtures:

Name	CAS No	EC No	Index No	Hazard statement	Content, %
Mixture of methacrylates	-	-	-	Skin Irrit. 2, H315; Skin Sens. 1, H317; Eye Irrit. 2, H319; STOT SE 3, H335	20-50

Full text of H- statements: see section 16.

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 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 immediate medical attention.

4.1.3. In case of skin contact

Take off contaminated clothing. Wash off with soap and plenty of water. Consult a physician. 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 medical attention.

4.1.5. If inhaled

Remove the casualty from the hazardous area and take him to the fresh air. If the casualty is not breathing: give artificial respiration, notify emergency physician immediately.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5: FIRE FIGHTING MEASURES**5.1. Extinguishing media**

Water spray, foam, carbon dioxide (CO₂), dry powder.

5.2. Special hazards arising from the substance or mixture

Heating or fire can release toxic gas.

5.3. Advice for fire fighters

Wear self-contained breathing apparatus for firefighting.

SECTION 6: ACCIDENTAL RELEASE MEASURES**6.1. Personal precautions, protective equipment and emergency procedures**

Use personal protective equipment. Avoid vapours formation. Avoid breathing vapours. Avoid contact with skin and eyes. Ensure adequate ventilation. Keep away from sources of ignition. Wash hands thoroughly with soap and water after handling.

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 spills with inert absorbent material. Collect spills and put it into appropriated container if it is safe to do. Dispose in a safe manner in accordance with national regulatory requirements.

6.4. Reference to other sections

For disposal see section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Use personal protective equipment when handling. Avoid contact with skin and eyes. Avoid breathing vapours. Take off all contaminated clothing immediately. Wash hands before breaks and immediately after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry, cool and well-ventilated place. Keep away from heat and direct sunlight. Do not freeze product. Storage temperature: 4-28°C.

7.3. Specific end uses

Dental use only.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters

8.1.1. 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. 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. 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. 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

Impervious clothing. 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

Wear self-contained breathing apparatus. 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	yellowish paste
Odour	specific
Flash point, °C	no data available
Initial boiling point, °C	no data available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

No data available.

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

High temperatures, direct sunlight.

10.5. Incompatible materials

No data available.

10.6. Hazard decomposition products

No data available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

11.1.1. Acute toxicity

No data available.

- 11.1.2. **Skin corrosion/irritation**
Uncured medical device may cause skin irritation.
- 11.1.3. **Serious eye damage/eye irritation**
Uncured medical device may cause serious eye irritation.
- 11.1.4. **Respiratory or skin sensitization**
Uncured medical device may cause an allergic skin reaction.
- 11.1.5. **Germ cell mutagenicity**
No data available.
- 11.1.6. **Carcinogenicity**
IARC: Titanium dioxide Group 2B – Possibly carcinogenic to humans.
- 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. Toxicity	no data available
12.2. Persistence and degradability	no data available
12.3. Bioaccumulative potential	no data available
12.4. Mobility in soil	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. **UN number**
ADR/RID: Not regulated. IMDG: Not regulated. IATA: Not regulated.
- 14.2. **UN proper shipping name**
ADR/RID: Not dangerous goods. IMDG: Not dangerous goods. IATA: Not dangerous goods.
- 14.3. **Transport hazard class(es)**
ADR/RID: - IMDG: - IATA: -
- 14.4. **Packing group**
ADR/RID: - IMDG: - IATA: -
- 14.5. **Environmental hazards**
ADR/RID: NO IMDG: Marine pollutant: NO IATA: NO
- 14.6. **Special precautions for user**
Read safety instructions, SDS and emergency procedures before handling. Ensure that persons transporting the product know what to do in the event of an accident of spillage.
- 14.7. **Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
No data available.

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: This product is 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 2018-08-01 version: whole document.
- 16.6. Abbreviations and acronyms used in the safety data sheet:
- 16.6.1. EC – European Commission
 - 16.6.2. EU – European Union
 - 16.6.3. GHS – Globally Harmonized System
 - 16.6.4. CLP – Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
 - 16.6.5. CAS No – Chemical Abstracts Service number
 - 16.6.6. EC No – EINECS and ELINCS Number (see also EINECS and ELINCS)
 - 16.6.7. EINECS – European Inventory of Existing Commercial Substances
 - 16.6.8. ELINCS – European List of Notified Chemical Substances
 - 16.6.9. NIOSH - National Institute for Occupational Safety and Health
 - 16.6.10. IARC – International Agency for Research on Cancer
 - 16.6.11. PBT - Persistent, Bio accumulative and toxic substance
 - 16.6.12. vPvB – Very Persistent and Very Bio accumulative
 - 16.6.13. ADR – European Agreement concerning the International Carriage of Dangerous Goods by Road
 - 16.6.14. RID – Regulations concerning the International Carriage of Dangerous Goods by Rail
 - 16.6.15. US – United states
 - 16.6.16. IMDG – International Marine Dangerous Goods
 - 16.6.17. IATA-DGR – International Air Transport Association Dangerous Goods Regulations
 - 16.6.18. LC50 – Lethal Concentration to 50 % of a test population
 - 16.6.19. 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: Warning**
- H302: Harmful if swallowed
- H315: Causes skin irritation
- H317: May cause an allergic skin reaction
- H319: Causes serious eye irritation
- H335: May cause respiratory irritation
- P261: Avoid breathing fume/vapours
- P264: Wash hands thoroughly after handling
- P270: Do not eat, drink or smoke when using this product
- P272: Contaminated work clothing should not be allowed out of the workplace
- P280: Wear protective gloves/protective clothing/eye protection/face protection
- P301+P312: IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell
- P330: Rinse mouth
- P302+P352: IF ON SKIN: Wash with plenty of water
- P321: Specific treatment: rinse with plenty of water
- P333+P313: If skin irritation or rash 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
- P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing
- P362+P364: Take off contaminated clothing and wash before reuse
- P501: Dispose of contents/container to as required by national regulatory requirements
- 16.9. Training advice: How to properly handle chemical substances / Mixtures employees must be trained in accordance with national requirements.