

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-BONDING LC^N
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 Aviacijos str. 28
LT-77103 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]

Flam. Liq. 2
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 **Danger**

Hazard statements

H225: Highly flammable liquid and vapour.
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 statements (prevention)

P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233: Keep container tightly closed.
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.

Precautionary statements (response)

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

P333+P313: If skin irritation or rash occurs: Get medical advice/ attention.
 P362+P364: Take off contaminated clothing and wash before reuse.
 P301+P312: IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell.
 P330: Rinse mouth.
 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.

Precautionary statements (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:**

<i>Name</i>	<i>CAS No</i>	<i>EC No</i>	<i>Index No</i>	<i>Hazard statement</i>	<i>Content, %</i>
2-Hydroxyethyl methacrylate	868-77-9	212-782-2	607-124-00-X	Skin Irrit. 2, H315; Skin Sens. 1, H317; Eye Irrit. 2, H319	30-50
Acetone	67-64-1	200-662-2	606-001-00-8	Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	10-30
Triethylamine	121-44-8	204-469-4	612-004-00-5	Flam. Liq. 2, H225; Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Corr. 1A, H314; Acute Tox. 4, H332; STOT SE 3, H335	<1

Full text of H- statements: see section 16.

3.2. Mixtures:

Not applicable.

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 immediate 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, alcohol resistant foam, dry chemical, carbon dioxide.

5.2. Special hazards arising from the substance or mixture

May form flammable vapours.

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. 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. Do not smoke, eat or drink in areas of use and storage.

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. 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 for mixture. ACGIH, NIOSH and OSHA have not developed exposure limits for this product.

Substance	CAS No.	WEL Short-term value	WEL Long-term value
Acetone	67-64-1	3620 mg/m ³ , 1500 ppm	1210m ³ , 500 ppm

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	clear, yellowish liquid
Odour	specific of acetone
Flash point, °C	2.5
Initial boiling point, °C	53±1

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

Protect from heat and 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

Acute systemic toxicity (ISO 10993-11) of final device extract in mice by systemic injection. No obvious body weight loss, no clinical signs of toxicity, no animals died during 72 hours observation period.

2-Hydroxyethyl methacrylate Cas No. 868-77-9

Oral LD50 >5000 mg/kg (rat)

Dermal LD50 >5000 mg/kg (rabbit)

Acetone Cas No. 67-64-1

Oral LD50 5800 mg/kg (rat)

Inhalation LC50 76 mg/l 4h (rat)

Dermal LD50 >7400 mg/kg (rat)

Triethylamine Cas No. 121-44-8

Oral LD50 730 mg/kg (rat)

Inhalation LC50 7.1 mg/l 4h (rat)

Dermal LD50 580 mg/kg (rabbit)

11.1.2. Skin corrosion/irritation

Intracutaneous reactivity (ISO 10993-10) of final device extract in rabbits by intracutaneous injection. Erythema scores: 0 and oedema scores 0 during 72 hours observation period.

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: 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. 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. Contaminated packaging dispose of as unused product. Do not remove the information from package.

SECTION 14: TRANSPORT INFORMATION

14.1. UN number

ADR/RID: UN2924

IMDG: UN2924

IATA: UN2924

14.2. UN proper shipping name

ADR/RID: FLAMMABLE LIQUID, CORROSIVE, N.O.S. (Acetone, Triethylamine), 3 (8), II, (D/E)

IMDG: FLAMMABLE LIQUID, CORROSIVE, N.O.S. (Acetone, Triethylamine)

IATA: Flammable liquid, corrosive, n.o.s. (Acetone, Triethylamine)

14.3. Transport hazard class(es)

ADR/RID: 3 (8)

IMDG: 3 (8)

IATA: 3 (8)

14.4. Packaging group

ADR/RID: II

IMDG: II

IATA: II

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: 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 2019-07-15 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: Danger

H225: Highly flammable liquid and vapour.

H302: Harmful if swallowed.

H312: Harmful in contact with skin.

H314: Causes severe skin burns and eye damage.

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H319: Causes serious eye irritation.

H332: Harmful if inhaled.

H335: May cause respiratory irritation.

H336: May cause drowsiness or dizziness.

P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

- P233: P233: Keep container tightly closed.
 - 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.
 - P302+P352: IF ON SKIN: Wash with plenty of water.
 - P333+P313: If skin irritation or rash occurs: Get medical advice/ attention.
 - P362+P364: Take off contaminated clothing and wash before reuse.
 - P301+P312: IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell.
 - P330: Rinse mouth.
 - 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.
 - 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.