

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-CORE (base)**
Chemical name -

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

Relevant identified uses Dual curing core build-up and post cementation material

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]

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

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 fume/vapours
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)

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

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

- 3.1. Substance:
Not applicable.

- 3.2. Mixture:

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	30-50
Benzoyl peroxide	94-36-0	202-327-6	617-008-00-0	Org. Perox. B, H241; Skin Sens. 1, H317; Eye Irrit. 2, H319	<1

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 inhaled**

Remove the casualty from the hazardous area and take him to the fresh air. If not breathing, give artificial respiration. Refer for immediate medical attention.

4.1.3. **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.

4.1.4. **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 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.

4.2. **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. Standard procedure for chemical fires.

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 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. Avoid vapours formation. Absorb using earth, sand or other inert material. Keep in suitable, closed containers for disposal. Never return spills in original containers for re-use. Ventilate contaminated area thoroughly.

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 eyes and skin. 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. Keep container tightly closed.

7.2. **Conditions for safe storage, including any incompatibilities**

Keep in cool, well ventilated place. Keep away from heat, direct sunlight. Storage temperature: Preferably not exceeding 2-8°C.

7.3. Specific end uses

Dual curing core build-up and post cementation material.

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.

Benzoyl peroxide: TWA 5 mg/m³.

8.2. Exposure controls

Install ventilation to prevent dust formatting. 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 chemical resistance (PVC, neoprene, rubber) gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with 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 standard EN 374.

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

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	paste
Odour	specific
Colour	yellowish
Boiling point	no data available
Flash point	no data available
Solubility	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

Protect from heat, 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. Intravenous injection – mice – 50 ml/kg bw/single dose of polar/non-polar extract – negative (no animals died during 72 hr observation period).

11.1.2. Skin corrosion/irritation

Intracutaneous reactivity (ISO 10993-10) of final device extract. Skin – rabbit – intracutaneous injection/0.2 ml per site of polar/non-polar extract – negative.

11.1.3. Serious eye damage/eye irritation

No data available.

11.1.4. Respiratory or skin sensitization

Delayed type hypersensitivity (ISO 10993-10) of final device extract. Skin – guinea pig – induction phase I (intradermal injection/0.1 ml per site); induction phase II (topical application/48h); challenge (topical application/24h) of polar/non-polar extract – negative.

11.1.5. Germ cell mutagenicity

No data available.

11.1.6. Carcinogenicity

IARC: Benzoyl peroxide Group 3 – Not classifiable as to its carcinogenicity to humans.

IARC: 2,6-di-tert-butyl-p-cresol Group 3 – Not classifiable as to its carcinogenicity to humans.

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

Subacute systemic toxicity (ISO 10993-11) of final device extract. Intravenous injection – mice – 20 ml/kg bw/1 dose per day for 7 days of polar extract – negative (no systemic toxicity was observed).

11.1.10. Aspiration hazard

No data available.

11.1.11. Additional Information

Ames mutagenicity test (ISO 10993-6) of final device extract – negative.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Ecotoxicity	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. Packaging group	ADR/RID: -	IMDG: -	IATA: -
14.5. Environmental hazards	ADR/RID: NO	IMDG Marine pollutant: NO	IATA: NO
14.6. Special precautions for user	No data available.		
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.		

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 x version: none.
- 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**
- H241: Heating may cause a fire or explosion
 - 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
 - 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
 - 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.