

SAFETY DATA SHEET

CHEMICAL SUBSTANCE / MIXTURE REGULATION (EC) No 1907/2006 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-PRO^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]

Aquatic Acute 1
Aquatic Chronic 1

2.2. Label elements

2.2.1. Labelling according to Regulation (EC) No 1272/2008 [CLP]

Pictograms



Signal word **Warning**

Hazard statement

H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

Precautionary statement (prevention)

P273: Avoid release to the environment.

Precautionary statement (response)

P391: Collect spillage.

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, %
Zinc oxide	1314-13-2	215-222-5	030-013-00-7	Aquatic Acute 1, H400; Aquatic Chronic 1, H410	20-50
Polymer	-	-	-	Skin Irrit. 2, H315; Eye Irrit. 2, H319	5-10

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 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 fumes.

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 dust formation. Avoid breathing dust. Avoid contact with skin and eyes. Ensure adequate ventilation. 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 dust formation. Keep in suitable, closed containers for disposal. Never return spills in original containers for re-use.

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

Zinc oxide dust: TWA 5 mg/m³ C 15 mg/m³; fume): TWA 5 mg/m³ ST 10 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	white/pink/greyish paste
Odour	pleasant
Flash point, °C	no data available
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 damage.

11.1.4. Respiratory or skin sensitization

No data available.

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: 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**
 - H400: Very toxic to aquatic life.
 - H410: Very toxic to aquatic life with long lasting effects.
 - H315: Causes skin irritation.
 - H319: Causes serious eye irritation.
 - P273: Avoid release to the environment.
 - P391: Collect spillage.
 - 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.