

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-GEL^N (gel)
Chemical name -

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

Relevant identified uses For professional use in dentistry 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]

Met. Corr. 1
Skin Corr. 1B

2.2. Label elements

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

Pictograms



Signal word **Danger**

Hazard statements

H290: May be corrosive to metals.
H314: Causes severe skin burns and eye damage.

Precautionary statements (prevention)

P234: Keep only in original container.
P260: Do not breathe vapours.
P264: Wash hands thoroughly after handling.
P280: Wear protective gloves / protective clothing / eye protection / face protection.
P390: Absorb spillage to prevent material damage.

Precautionary statements (response)

P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P310: Immediately call a POISON CENTER or doctor/physician.
P363: Wash contaminated clothing before reuse.

Precaution statements (disposal)

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

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

- 3.1. Substance:
Not applicable.

- 3.2. Mixture:

Name	CAS No	EC No	Index No	Hazard statement	Content, %
Phosphoric acid	7664-38-2	231-633-2	015-011-00-6	Met. Corr. 1, H290; Skin Corr. 1B, H314	35-40

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. Subsequently, have the casualty drink 1 - 2 glasses of water immediately. Do not try to neutralize with bases, no charcoal. 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

Material may be corrosive to the mucous membranes and upper respiratory tract, eyes, and skin.

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, dry chemical foam.

5.2. Special hazards arising from the substance or mixture

Hydrogen gas may be released in contact with metals.

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 breathing vapours. Ensure adequate ventilation.

6.2. Environmental precautions

Do NOT let enter the environment if safe to do so.

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**

Corrosive. Use personal protective equipment. Avoid contact with eyes and skin. Ensure adequate ventilation. 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 container tightly closed in a dry, cool and well-ventilated place. Keep away from heat and direct sunlight. Storage temperature: preferably not exceeding 28°C.

7.3. Specific end uses

For professional use in dentistry 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.	OEL Short-term value	OEL Long-term value
Phosphoric acid	7664-38-2	3 mg/m ³	1 mg/m ³

8.2. Exposure controls

Provide adequate ventilation, including appropriate local extraction, to ensure that the defined occupational exposure limit is not exceeded. 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. 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

Keep working clothes separately. 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	blue/green gel
Odour	specific
pH	<1
Viscosity, cP	6000-10000
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

No data available.

10.5. Incompatible materials

Strong bases, metals.

10.6. Hazard decomposition products

At high temperature may liberate oxides of phosphorus.

SECTION 11: TOXICOLOGICAL INFORMATION**11.1. Information on toxicological effects****11.1.1. Acute toxicity**

Phosphoric acid Cas No. 7664-38-2
Oral LD50 2600 mg/kg (rat)
Inhalation LC50 193 mg/m³ (guinea pig)
Dermal LD50 >2000 mg/kg (rabbit)

11.1.2. Skin corrosion/irritation

Primary skin irritation (ISO 10993-10) by direct application in rabbits. Erythema and oedema scores: 0.06 during 72 hours observation period. Result: skin irritation response: negligible.

11.1.3. Eye damage/eye irritation

No data available.

11.1.4. Respiratory or skin sensitization

Delayed type hypersensitivity (ISO 10993-10) by maximization test in guinea pigs. Result: not sensitizing.

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. 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: UN1805

IMDG: UN1805

IATA: UN1805

14.2. UN proper shipping name

ADR/RID: PHOSPHORIC ACID, SOLUTION, 8, III, (E)

IMDG: PHOSPHORIC ACID, SOLUTION

IATA: Phosphoric acid, solution

14.3. Transport hazard class(es)

ADR/RID: 8

IMDG: 8

IATA: 8

14.4. Packaging group

ADR/RID: III

IMDG: III

IATA: III

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

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: 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: company address.
- 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**
- H290: May be corrosive to metals.
- H314: Causes severe skin burns and eye damage.
- P234: Keep only in original container.
- P260: Do not breathe vapours.
- P264: Wash hands thoroughly after handling.
- P280: Wear protective gloves / protective clothing / eye protection / face protection.
- P390: Absorb spillage to prevent material damage.
- P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
- P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
- P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P310: Immediately call a POISON CENTER or doctor/physician.
- P363: Wash contaminated clothing 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.