

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

1.1. Product identifiers

Product names	i-STONE ORTO
Chemical name	-
Identified uses	Synthetic hard dental plaster for orthodontics type III

1.2. Details of the supplier of the safety data sheet

Company	UAB "Medicinos linija"
Address	Karaliaučiaus str. 29 LT-78374 Šiauliai, Lithuania
Telephone	+370 41 553 553
Fax	+370 41 553 551
E-mail address	dental@i-dental.lt

1.3. Emergency telephone number

Emergency telephone number (Available only during office hours)	+370 41 553 553
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SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]

No significant hazard

2.2. Label elements

Pictograms No pictograms

Signal word No signal word

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

- 3.1. Information on hazardous ingredients:
Blend of gypsum. Contains no hazardous materials.

SECTION 4: FIRST AID MEASURES

4.1. General advice

In doubt, consult a physician. Show this safety data sheet to the doctor in attendance.

4.2. 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.** Drink plenty of water (approx. 500 ml). Refer for medical attention if symptoms persist.

4.3. 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 if symptoms persist.

4.4. If inhaled

Remove the casualty from the hazardous area and take him to the fresh air. If not breathing, give artificial respiration. Keep warm and at rest. Refer for medical attention if symptoms persist.

4.5. In case of skin contact

Take off contaminated clothing. Wash off with plenty of water. If symptoms occur obtain medical attention. Wash contaminated clothing before reuse.

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

No data available.

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

No data available.

SECTION 5: FIRE FIGHTING MEASURES

5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions: CO₂, extinguishing powder or water jet. Fight larger fires with foam.

5.2. Unsuitable extinguishing media

No data available.

- 5.3. **Advice for fire fighters**
Standard procedure for chemical fires.
- 5.4. **Special hazards arising from the substance or mixture**
Fire can cause release of Sulfur trioxide (SO₃).

SECTION 6: ACCIDENTAL RELEASE MEASURES

- 6.1. **Personal precautions, protective equipment and emergency procedures**
Use personal protective equipment. Avoid causing dust. Ensure adequate ventilation.
- 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. Sweep up, transfer to suitable, labelled container for disposal and dispose. Clean spillage area thoroughly with plenty of water.
- 6.4. **Reference to other sections**
For disposal see section 13.

SECTION 7: HANDLING AND STORAGE

- 7.1. **Precautions for safe handling**
No special precautions necessary if used properly. Use personal protective equipment. Keep tightly closed. 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 in dry, cool, well ventilated place. Keep away from humidity, heat and direct sunlight. Storage temperature: Preferably not exceeding 28°C.
- 7.3. **Specific end uses**
Synthetic hard dental plaster for orthodontics type III.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Exposure limit values

Substance	CAS No.	TGRS 900
General dust exposure limit, measured as alveolic part	-	3 mg/m ³

- 8.2. **Exposure controls**
Provide adequate ventilation. Storage properly (p.7).
Preventive medical check-ups should be arranged.
- 8.3. **Appropriate engineering controls**
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday. Avoid contact with eyes.
- 8.4. **Personal protective equipment**
- 8.4.1. **Eye/face protection**
Wear eye / face protection equipment. Safety glasses with side-shields, conforming to EN 166.
- 8.4.2. **Hand protection**
Not required handle with gloves. If gloves are used the selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
- 8.4.3. **Skin protection**
Keep working clothes separately. Take off contaminated clothing immediately. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
- 8.4.4. **Respiratory protection**
Not necessary with efficient local exhaust. If exposition to dust is possible, use breathing protective mask (short term filter ABEK; long time exposure filter P1 (for solid particles)).

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

- 9.1. **General information**
- | | |
|------------|-------------|
| Appearance | solid |
| Odour | odourless |
| Colour | extra white |
- 9.2. **Important health, safety and environment information**
- | | |
|---------------|-------------------|
| Melting point | no data available |
|---------------|-------------------|

SECTION 10: STABILITY AND REACTIVITY

- 10.1. **Stability**
Stable under normal conditions.
- 10.2. **Conditions to avoid**
Protect from humidity, heat and direct sunlight.
- 10.3. **Materials to avoid**
No data available.
- 10.4. **Hazard decomposition products**

Sulphur trioxide (SO₃).**SECTION 11: TOXICOLOGICAL INFORMATION****11.1. Possible dangerous to health effects**

No data available regarding specific product.

11.2. Germ cell mutagenicity

No data available.

11.3. 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.

11.4. Reproductive toxicity

No data available.

11.5. Specific target organ toxicity - single exposure**Inhalation:** Unlikely to be hazardous by inhalation.**Skin contact:** No irritant effect.**Eye contact:** May cause moderate irritation**Ingestion:** Unlikely to be hazardous by ingestion.**11.6. Specific target organ toxicity - repeated exposure**

No data available.

11.7. Aspiration hazard

No data available.

11.8. Additional Information

None of effects are likely to occur in humans, provided exposure is maintained at or below occupational exposure limit.

11.9. Toxicity data

No data available.

SECTION 12: ECOLOGICAL INFORMATION**12.1. Ecotoxicity**

No data available regarding specific product

12.2. Mobility

No data available

12.3. Persistence and degradability

Inorganic salts are basically not biodegradable. Easy elimination possible by flocculation or adsorption by sludge.

12.4. Bio accumulative potential

Due to the distribution coefficient n-octanol/water an accumulation in organisms is not expected.

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 packagings dispose of as unused product. Do not remove the information from package.

SECTION 14: TRANSPORT INFORMATION

14.1. The product is not classified as dangerous for carriage

SECTION 15: REGULATORY INFORMATION

15.1. This safety datasheet complies with the requirements of Regulation (EC) No 1907/2006 as amended by Regulation (EU) No 453/2010.

15.2. Other Regulations: EINECS: Components of mixture are on the European Inventory of Existing Commercial Chemical Substances.

15.3. This safety data sheet information is not a professional risk assessment.

15.4. Safety, health and environmental regulations/legislation specific for the substance or mixture

No data available.

15.5. Chemical Safety Assessment

No data available.

15.6. Health, safety and environmental information

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 ___ - ___ version: whole document.
- 16.6. Abbreviations and acronyms used in the safety data sheet:
- 16.6.1. EC – European Commission
 - 16.6.2. GHS – Globally Harmonized System
 - 16.6.3. CLP – Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
 - 16.6.4. CAS No – Chemical Abstracts Service number
 - 16.6.5. EC No – EINECS and ELINCS Number (see also EINECS and ELINCS)
 - 16.6.6. PBT - Persistent, Bio accumulative and toxic substance
 - 16.6.7. VPvB – Very Persistent and Very Bio accumulative
 - 16.6.8. ADR – European Agreement concerning the International Carriage of Dangerous Goods by Road
 - 16.6.9. UN – United Nations
 - 16.6.10. LC50 – Lethal Concentration to 50 % of a test population
 - 16.6.11. 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: None.
- 16.9. Training advice: How to properly handle chemical substances / mixtures employees must be trained in accordance with national requirements.