

Safety Data Sheet

according to UK REACH Regulation

FINOCLASSIC ORTHO STONE Orthodontics Hard Plaster

Revision date: 08.03.2024

10050 / 10051

Page 1 of 9

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

FINOCLASSIC ORTHO STONE Orthodontics Hard Plaster

REF

REF 10050 / 10051

| Product group: | Calciumverbindungen |
|----------------|---------------------|
| CAS No: | 7778-18-9 |
| EC No: | 231-900-3 |

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

Use of the substance/mixture

For the creation of anatomic casts and control models in orthodontic works. Also suitable for counter bite and repair models.

1.3. Details of the supplier of the safety data sheet

| Company name: | FINO GmbH | |
|--------------------------|---------------------------------|--|
| Street: | Mangelsfeld 18 | |
| Place: | D-97708 Bad Bocklet | |
| Telephone: | +49-97 08-90 94 20 | Telefax:+49-97 08-90 94 21 |
| e-mail: | info@fino.com | Internet: www.fino.com |
| Contact person: | Joachim Mahlmeister | Telephone: +49-97 08-90 94 20 |
| e-mail: | info@fino.com | |
| Responsible Department: | This number can only be reached | d during our office hours, Monday to Friday from |
| | 8 a.m. to 5 p.m. | |
| 1.4. Emergency telephone | +49-89-1 92 40 | |
| number: | POISON CENTER München | |
| | 24 hour(s) 7 day(s) | |

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

2.2. Label elements

GB CLP Regulation

Hazard components for labelling

Void

Special labelling of certain mixtures

none

Additional advice on labelling

According to EC directives or the corresponding national regulations the product does not have to be labelled. No risks worthy of mention. Please observe the information on the safety data sheet at all times.

2.3. Other hazards

Results of PBT and vPvB assessment not applicable.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Mixture from the below listed substances with harmless additives. Calcium sulphate in different hydrate levels without e.g. with additives.

| Sum formula: | CaSO4; CaO4S |
|-------------------|--------------|
| Molecular weight: | 136,11 g/mol |



FINOCLASSIC ORTHO STONE Orthodontics Hard Plaster

Revision date: 08.03.2024

10050 / 10051

Page 2 of 9

Hazardous components

| CAS No | Chemical name | Chemical name | | | | |
|-----------|------------------------------------|---------------|--|------------|--|--|
| | EC No Index No REACH No | | | | | |
| | Classification (GB CLP Regulation) | | | | | |
| 7778-18-9 | Calcium sulphate | | | 80 - 100 % | | |
| | 231-900-3 | | | | | |
| | | | | | | |

Full text of H and EUH statements: see section 16.

REF

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

No specific if used according to specifications. Notes for the doctor: Allergic reactions Not known.

After inhalation

Provide fresh air. If breathing is irregular or stopped, administer artificial respiration. If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical advice/attention.

After contact with skin

After contact with skin, take off immediately all contaminated clothing, and wash immediately with plenty of water and soap. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

After contact with eyes

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

After ingestion

Induce vomiting when the affected person is not unconscious. Get medical advice/attention.

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

No known symptoms to date.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Extinguishing powder, Water spray jet, alcohol resistant foam Co-ordinate fire-fighting measures to the fire surroundings.

Unsuitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

Sulphur dioxide (SO2)

5.3. Advice for firefighters

The product itself does not burn. Co-ordinate fire-fighting measures to the fire surroundings. Product sets when in contact with water. In case of fire: Wear self-contained breathing apparatus. Full protection suit

SECTION 6: Accidental release measures



Safety Data Sheet

according to UK REACH Regulation

FINOCLASSIC ORTHO STONE Orthodontics Hard Plaster

Revision date: 08.03.2024

REF

10050 / 10051

Page 3 of 9

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Provide adequate ventilation. Use personal protection equipment. Avoid dust formation. Special danger of slipping by leaking/spilling product.

For non-emergency personnel

Emergency procedures

Remove persons to safety. Remove victim out of the danger area.

The danger areas must be delimited and identified using relevant warning and safety signs.

For emergency responders

Use personal protection equipment.

6.2. Environmental precautions

Do not allow to enter sewers/surface or ground water.

6.3. Methods and material for containment and cleaning up

For containment

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Take up mechanically.

For cleaning up

Collect in closed and suitable containers for disposal.

Wash contaminated clothing before reuse.

6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Treat the recovered material as prescribed in the section on waste disposal. Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

No specific if used according to specifications. When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work. Used working clothes should not be worn outside the work area.

Advice on protection against fire and explosion

The product itself does not burn. No special fire protection measures are necessary.

Advice on general occupational hygiene

The usual precautionary measures are to be adhered to when handling chemicals. Keep away from food, drink and animal feedingstuffs. Wash hands before breaks and after work.

When using do not eat or drink.

Further information on handling

Avoid: Generation/formation of dust Inhalation of dust/particles Eye contact

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

No specific if used according to specifications. If handled uncovered, arrangements with local exhaust ventilation should be used if possible. No special environmental measures are necessary.

Hints on joint storage

Not required.

Further information on storage conditions

Store in a dry place.

Keep/Store only in original container.



FINOCLASSIC ORTHO STONE Orthodontics Hard Plaster

Revision date: 08.03.2024

REF

10050 / 10051

Page 4 of 9

Betriebssicherheitsverordnung (BetrSichV) ---

7.3. Specific end use(s)

Creation of partial denture frames

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

DNEL/DMEL values

| CAS No | Substance | | | | | |
|--------------------------|------------------|----------------|----------|-------------------------|--|--|
| DNEL type | | Exposure route | Effect | Value | | |
| 7778-18-9 | Calcium sulphate | | | | | |
| Worker DNE | L, long-term | inhalation | systemic | 21.17 mg/m ³ | | |
| Worker DNE | L, acute | inhalation | systemic | 5.082 mg/m ³ | | |
| Consumer D | NEL, long-term | inhalation | systemic | 5.29 mg/m ³ | | |
| Consumer D | NEL, acute | inhalation | systemic | 3.811 mg/m ³ | | |
| Consumer DNEL, long-term | | oral | systemic | 1.52 mg/kg bw/day | | |
| Consumer D | NEL, acute | oral | systemic | 11.4 mg/kg bw/dav | | |

8.2. Exposure controls





Appropriate engineering controls

Avoid dust formation. Take up dust-free and set down dust-free. Wear eye/face protection. Wear suitable protective clothing, gloves and eye/face protection.

Individual protection measures, such as personal protective equipment

Eye/face protection

Protective goggles with side protection recommendable.

Hand protection

Repeated exposure may cause skin dryness or cracking. Wear suitable gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation. The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

The precise time of rupture can be found out from the manufacturer of the protective gloves and must be observed.

Recommended material: Nitrile Gloves

Skin protection

Wear suitable protective clothing.

Respiratory protection

Measures to prevent aerosol and dust generation Half-face mask or quarter facepiece: maximum use concentration for substances with exposure limits: P1 filter: up to a max. of 4 times the exposure limit. P2 filter: up to a max. of 10 times the exposure limit. P3 filter: up to a max. of 30 times the expo.



Safety Data Sheet

according to UK REACH Regulation

FINOCLASSIC ORTHO STONE Orthodontics Hard Plaster

Revision date: 08.03.2024

10050 / 10051

Page 5 of 9

Environmental exposure controls

Do not allow to enter into surface water or drains.

REF

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| Physical state: Colour: | Powder |
|--|--|
| Odour: | odourless |
| Changes in the physical state Melting point/freezing point: | 1450 °C |
| Boiling point or initial boiling point ar boiling range: | |
| Softening point: | not applicable |
| Flash point: | not applicable |
| Flammability Solid/liquid: | not applicable |
| Explosive properties not explosive. | |
| Lower explosion limits: | |
| Upper explosion limits: | |
| Auto-ignition temperature: | not applicable |
| Self-ignition temperature Solid: | Product is not selfigniting. |
| Decomposition temperature: | approx. 1000 °C |
| pH-Value: | 7-9 |
| Viscosity / dynamic: | not determined |
| Water solubility: (at 20 °C) | approx. 2 g/L |
| Partition coefficient n-octanol/water: | Product/Substance is inorganic. |
| Vapour pressure: | not applicable |
| Density: Bulk density: | not determined 600-1200 kg/m ³ |
| Relative vapour density: | not determined |
| 9.2. Other information | |
| Information with regard to physica Sustaining combustion: | al hazard classes No data available |
| Other safety characteristics | |
| Solvent separation test: | Powder is hygroscopic, absorbs water and sets by releasing heat. |
| Solvent content: | Organic solvents: 0,0 % |
| Solid content: | 100% |
| Evaporation rate: | not determined |
| | |

Further Information

SECTION 10: Stability and reactivity



FINOCLASSIC ORTHO STONE Orthodontics Hard Plaster

Revision date: 08.03.2024

10050 / 10051

Page 6 of 9

10.1. Reactivity

Not known.

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

Formation of: Carbon dioxide in aqueous solution a mixture of 95% water and 5% sodium carbonate

10.5. Incompatible materials

Not known.

10.6. Hazardous decomposition products

Decomposition takes place from temperatures above: 1000 °C Decomposition under formation of: Sulphur trioxide + Calcium oxide

REF

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in GB CLP Regulation

Acute toxicity

Based on available data, the classification criteria are not met.

No effects known. No risk known. There are no data available on the preparation/mixture itself.

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Additional information on tests

Based on our experiences and information the product does not cause harmful health effects if handled according to specifications and used according to indications.

Practical experience

No known symptoms to date. No effects known.

11.2. Information on other hazards

Other information

No known symptoms to date. No effects known.

SECTION 12: Ecological information

12.2. Persistence and degradability

The product hydrolyses quickly in the presence of water to: Putty, based on calcium sulphate, not labelled The individual components are poorly eliminated from water. Excretion/elimination none. The methods for determining the biological degradability are not applicable to inorganic substances. Inorganic product which is not eliminable from water through biological cleaning processes.



FINOCLASSIC ORTHO STONE Orthodontics Hard Plaster

| Revision date: | 08.03.2024 REF | 10050 / 10051 | | | Page 7 of 9 |
|----------------|------------------------|---------------|---|--------|-------------|
| CAS No | Chemical name | | | | |
| | Method | Value | d | Source | |
| | Evaluation | | | | |
| 7778-18-9 | Calcium sulphate | | | | |
| | sewage treatment plant | 100 mg/l | | | |

12.3. Bioaccumulative potential

Based on the n-octanol/water partition coefficient accumulation in organisms is not expected. No indication of bioaccumulation potential. According to experiences this product is inert and not degradable.

12.4. Mobility in soil

Soluble in: Water If product enters soil, it will be mobile and may contaminate groundwater.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

This substance does not meet the criteria for classification as PBT or vPvB.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No effects known. No risk known.

Further information

Water hazard class slightly hazardous to water

Don't let flow into the ground water, in waters or the sewage system undiluted resp. in larger quantities.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Dispose of waste according to applicable legislation.

List of Wastes Code - residues/unused products

101306 WASTES FROM THERMAL PROCESSES; wastes from manufacture of cement, lime and plaster and articles and products made from them; particulates and dust (except 10 13 12 and 10 13 13)

List of Wastes Code - used product

170802 CONSTRUCTION AND DEMOLITION WASTES (INCLUDING EXCAVATED SOIL FROM CONTAMINATED SITES); gypsum-based construction material; gypsum-based construction materials other than those mentioned in 17 08 01

List of Wastes Code - contaminated packaging

101206 WASTES FROM THERMAL PROCESSES; wastes from manufacture of ceramic goods, bricks, tiles and construction products; discarded moulds

Contaminated packaging

Contaminated packages must be completely emptied and can be re-used following proper cleaning. Dispose of waste according to applicable legislation.

SECTION 14: Transport information

Land transport (ADR/RID)

| 14.1. UN number or ID number: | UN 0000 |
|-----------------------------------|--|
| 14.2. UN proper shipping name: | No dangerous good in sense of this transport regulation. |
| 14.3. Transport hazard class(es): | No dangerous good in sense of this transport regulation. |
| 14.4. Packing group: | No dangerous good in sense of this transport regulation. |
| Inland waterways transport (ADN) | |
| 14.1. UN number or ID number: | UN 0000 |
| 14.2. UN proper shipping name: | No dangerous good in sense of this transport regulation. |



| FINOCLASSIC ORTHO STONE | Orthodontics Hard Plaster |
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|--|---|-------------|
| Revision date: 08.03.2024 | 10050 / 10051 | Page 8 of 9 |
| 14.3. Transport hazard class(es): | No dangerous good in sense of this transport regulation. | |
| 14.4. Packing group: | No dangerous good in sense of this transport regulation. | |
| Marine transport (IMDG) | | |
| 14.1. UN number or ID number: | UN 0000 | |
| 14.2. UN proper shipping name: | No dangerous good in sense of this transport regulation. | |
| <u>14.3. Transport hazard class(es):</u> 14.4. Packing group: | No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. | |
| Air transport (ICAO-TI/IATA-DGR) | | |
| <u>14.1. UN number or ID number:</u> | UN 0000 | |
| 14.2. UN proper shipping name: | No dangerous good in sense of this transport regulation. | |
| 14.3. Transport hazard class(es): | No dangerous good in sense of this transport regulation. | |
| 14.4. Packing group: | No dangerous good in sense of this transport regulation. | |
| 14.5. Environmental hazards | | |
| ENVIRONMENTALLY HAZARDOUS: | No | |
| 14.6. Special precautions for user | | |
| No special measures are necessary. | | |
| 14.7. Maritime transport in bulk according | to IMO instruments | |
| No special precautionary measures. | | |
| SECTION 15: Regulatory information | | |
| 15.1. Safety, health and environmental reg | gulations/legislation specific for the substance or mixture | |
| EU regulatory information | | |
| 2010/75/EU (VOC): | no classification | |
| 2004/42/EC (VOC): | no classification | |
| Information according to 2012/18/EU | Not subject to 2012/18/EU (SEVESO III) | |
| (SEVESO III): | | |
| Additional information: | 0 | |
| Additional information | | |
| | rresponding national regulations the product does not have to be labelled. rdous according to Directive 1999/45/EC. | |
| National regulatory information | | |
| Employment restrictions: | Observe restrictions to employment for juveniles according to the 'juver work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers. | |
| Water hazard class (D): | 1 - slightly hazardous to water | |
| 15.2. Chemical safety assessment | | |

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

* Data changed compared with the previous version.

Abbreviations and acronyms

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail) "IATA-DGR: Dangerous Goods Regulations by the ""International Air Transport Association"" (IATA)" ICAO: International Civil Aviation Organization

"ICAO-TI: Technical Instructions by the ""International Civil Aviation Organization"" (ICAO)"

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement



INOCLASSIC ORTHO STONE Orthodontics Hard Plaster

| evision date: 08.03.2024 | REF | 10050 / 10051 | Page 9 of 9 |
|----------------------------|------------------------|-----------------------------------|-------------|
| concerning the Internation | onal Carriage of Dang | erous Goods by Road) | |
| IMDG: International Mar | itime Code for Dange | rous Goods | |
| IATA: International Air T | ransport Association | | |
| GHS: Globally Harmoniz | ed System of Classifi | cation and Labelling of Chemicals | |
| EINECS: European Inve | ntory of Existing Com | mercial Chemical Substances | |
| ELINCS: European List | of Notified Chemical S | Substances | |
| CAS: Chemical Abstract | s Service (division of | the American Chemical Society) | |
| VOC: Volatile Organic C | ompounds (USA, EU) | | |
| PBT: Persistent, Bioacc | umulative and Toxic | | |
| SVHC: Substances of V | ery High Concern | | |
| vPvB: very Persistent ar | nd very Bioaccumulati | ve | |
| LC50: Lethal concentrat | ion, 50 percent | | |
| LD50: Lethal dose, 50 p | ercent | | |

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material. The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights.

Identified uses

| No | Short title | LCS | SU | PC | PROC | ERC | AC | TF | Specification |
|--|-------------|-------|--------|----|------|-----|----|----|---------------|
| 1 | Gypsum | PW, C | 13, 19 | 9b | 19 | - | - | - | 7778-18-9 |
| LCS: Life cycle stages SU: Sectors of use | | | | | | | | | |
| PC: Product categories PROC: Process categories | | | | | | | | | |
| ERC: Environmental release categories AC: Article categories | | | | | | | | | |
| TF: Technical functions | | | | | | | | | |

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)