

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

1.1. Product identifier

Product form : Mixture
Trade name : ORTOGUIX-PLASTER
Product code : 1151

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only
Dental laboratories
Non-sterile product

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

FAMADENT S.L.U.
Garrotxa, 6 Polígono Empordà Internacional
ES- 17469 Vilamalla
España
T +34 972 526 169
protechno@protechno.com - www.protechno.com
E-mail address of competent person responsible for the SDS : SDS@protechno.com

1.4. Emergency telephone number

Emergency number : +34 972 526 169

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

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

No labelling applicable

2.3. Other hazards

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

ORTOGUIX-PLASTER

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

3.2. Mixtures

Comments : This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II
However a safety data sheet is being supplied for it upon request as it contains a substance for which there is a Union workplace exposure limit

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Calcium sulfate, hemihydrate	CAS-No.: 10034-76-1 EC-No.: 600-067-1 REACH-no: 01-2119444918-0215	≥ 80	Not classified

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact : Wash skin with plenty of water.
First-aid measures after eye contact : Rinse cautiously with water for several minutes. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion : Rinse mouth out with water. If you feel unwell, seek medical advice.

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

No additional information available

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 : Water spray. Dry powder. Foam.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid dust formation.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

ORTOGUIX-PLASTER

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Mechanically recover the product.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid dust formation. Use only by appropriate trained persons.
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a dry place. Keep cool. Only store product in original container. Keep container closed when not in use. Protect from moisture.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

Calcium sulfate, hemihydrate (10034-76-1)	
United Kingdom - Occupational Exposure Limits	
Local name	Calcium sulfate hemihydrate
WEL TWA (OEL TWA) [1]	10 mg/m ³ (inhalable fraction)
Regulatory reference	Source: Occupational Safety and Health Administration (OSHA)

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Common hygienic measures in a dental laboratory. Ensure good ventilation of the work station. Do not breathe dust.

ORTOGUIX-PLASTER

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:

Eye protection (goggles)

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves. Since the product consists of several substances, the durability of the glove material cannot be estimated and needs to be tested before use. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer

8.2.2.3. Respiratory protection

Respiratory protection:

In case of inadequate ventilation wear respiratory protection.

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white.
Appearance	: dust.
Odour	: Characteristic.
Odour threshold	: Not available
Melting point	: > 1400 °C
Freezing point	: Not applicable
Boiling point	: Not available
Flammability	: Non flammable.
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50 °C	: Not available
Density	: 2.5 kg/l
Relative density	: Not applicable
Relative vapour density at 20 °C	: Not applicable
Particle size	: Not available
Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available

ORTOGUIX-PLASTER

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Particle dustiness : Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Based on available data, the classification criteria are not met
Acute toxicity (dermal)	: Based on available data, the classification criteria are not met
Acute toxicity (inhalation)	: Based on available data, the classification criteria are not met
Skin corrosion/irritation	: Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	: Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Based on available data, the classification criteria are not met
Carcinogenicity	: Based on available data, the classification criteria are not met
Reproductive toxicity	: 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

Calcium sulfate, hemihydrate (10034-76-1)

Viscosity, kinematic	Not applicable
----------------------	----------------

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

11.2.2. Other information

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met

ORTOGUIX-PLASTER

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute) : Not classified
Hazardous to the aquatic environment, long-term (chronic) : Not classified

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / RID

ADR	IMDG	IATA	RID
14.1. UN number or ID number			
Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name			
Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)			
Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group			
Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards			
Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available			

ORTOGUIX-PLASTER

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no REACH substances with Annex XVII restrictions

REACH Annex XIV (Authorisation List)

Contains no REACH Annex XIV substances

REACH Candidate List (SVHC)

Contains no substance on the REACH candidate list

PIC Regulation (Prior Informed Consent)

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

POP Regulation (Persistent Organic Pollutants)

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Ozone Regulation (1005/2009)

Contains no substance subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.

Explosives Precursors Regulation (2019/1148)

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on drug precursors)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

SDS EU format according to COMMISSION REGULATION (EU) 2020/878.

ORTOGUIX-PLASTER

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Abbreviations and acronyms:	
	Spain - BLV
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
DPD	Dangerous Preparations Directive 1999/45/EC
EC50	Median effective concentration
DSD	Dangerous Substances Directive 67/548/EEC
SDS	Safety Data Sheet
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
vPvB	Very Persistent and Very Bioaccumulative
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
TLM	Median Tolerance Limit

Data sources	: Classification according to Classification, Labelling and Packaging of Substances and Mixtures (SEA) Regulation published in the Official Journal numbered 28848 on December 11, 2013. REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
Training advice	: Normal use of this product shall imply use in accordance with the instructions on the packaging.
Other information	: Non-sterile product.

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.