



## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 11/20/2017 Revision date: 8/30/2022 Supersedes version of: 11/20/2017 Version: 3.0

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

## **1.1. Product identifier**

Product code

Product form		
Trade name		

: Mixture : QUICK-ROCK : 1160

#### 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 : <u>SDS@protechno.com</u>

#### **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 ≥ 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

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3.2. Mixtures			
Comments	<ul> <li>This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II</li> <li>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</li> </ul>		
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
Calcium carbonate	CAS-No.: 471-34-1 EC-No.: 207-439-9	10 – 50	Not classified

SECTION 4: First aid measures			
4.1. Description of first aid measures	i de la constante de la constan		
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.		

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 subs	tance 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 person				

No additional information available

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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".			
6.2. Environmental precautions				
Avoid release to the environment.				
6.3. Methods and material for containment and cleaning up				
Methods for cleaning up Other information	<ul><li>Mechanically recover the product.</li><li>Dispose of materials or solid residues at an authorized site.</li></ul>			
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

Calcium sulfate, hemihydrate (10034-76-1)		
United Kingdom - Occupational Exposure Limits		
Local name	Calcium sulfate hemihydrate	
WEL TWA (OEL TWA) [1]	10 mg/m³ (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

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## 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.

## 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 ch	nemical 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	
рН	: 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	

: Not applicable

Not applicableNot available

## 8/30/2022 (Revision date)

Relative vapour density at 20 °C

Relative density

Particle size

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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
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

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	ECTION	40. Ctability	y and reactivity
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## 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

STOT-single exposure STOT-repeated exposure Aspiration hazard	<ul> <li>Based on available data, the classification criteria are not met</li> <li>Based on available data, the classification criteria are not met</li> <li>Based on available data, the classification criteria are not met</li> </ul>
Reproductive toxicity	: Based on available data, the classification criteria are not met
Germ cell mutagenicity Carcinogenicity	<ul> <li>Based on available data, the classification criteria are not met</li> <li>Based on available data, the classification criteria are not met</li> </ul>
Respiratory or skin sensitisation	: Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Based on available data, the classification criteria are not met
Skin corrosion/irritation	: Based on available data, the classification criteria are not met
Acute toxicity (oral) Acute toxicity (dermal) Acute toxicity (inhalation)	<ul> <li>Based on available data, the classification criteria are not met</li> <li>Based on available data, the classification criteria are not met</li> <li>Based on available data, the classification criteria are not met</li> </ul>

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## **11.2. Information on other hazards**

## 11.2.1. Endocrine disrupting properties

## 11.2.2. Other information

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

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 assessmen	t
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**

ADR	IMDG	ΙΑΤΑ	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

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ADR	IMDG	ΙΑΤΑ	RID
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			

## **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)

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## 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.

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	
ΙΑΤΑ	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	
РВТ	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.

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## 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.