

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

### 1.1. Product identifier

Product form : Mixture  
Trade name : MALAKIT  
Product code : 1110

### 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  
17469 Vilamalla - España  
T +34 972 526 169  
[protechno@protechno.com](mailto:protechno@protechno.com) - [www.protechno.com](http://www.protechno.com)  
E-mail address of competent person responsible for the SDS : [SDS@protechno.com](mailto: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

Other hazards not contributing to the classification : The product does not meet the PBT and vPvB classification criteria.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 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

# MALAKIT

## Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

### 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".

#### 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

No additional information available

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According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

### 8.2. Exposure controls

#### Appropriate engineering controls:

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

#### Hand protection:

Wear protective gloves.

#### Eye protection:

Where excessive dust may result, wear goggles

#### Skin and body protection:

Wear suitable protective clothing

#### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. Wear appropriate mask

#### Personal protective equipment symbol(s):



#### 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
Appearance	: dust.
Colour	: (Dependent on composition).
Odour	: odourless.
Odour threshold	: No data available
pH	: 6 - 7 Aqueous solution
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 1450 °C
Freezing point	: Not applicable
Boiling point	: No data available
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: > 1000 °C
Flammability (solid, gas)	: Non flammable.
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: Not applicable
Density	: 2,5 kg/l
Solubility	: Water: 2 g/l at 20 °C
Log Pow	: No data available
Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: Not applicable

### 9.2. Other information

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.

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### 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 toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified
	pH: 6 - 7 Aqueous solution
Serious eye damage/irritation	: Not classified
	pH: 6 - 7 Aqueous solution
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

## 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.
Acute aquatic toxicity	: Not classified
Chronic aquatic toxicity	: 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. 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.
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### SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	RID
<b>14.1. UN number</b>			
Not regulated	Not regulated	Not regulated	Not regulated
<b>14.2. UN proper shipping name</b>			
Not regulated	Not regulated	Not regulated	Not regulated
<b>14.3. Transport hazard class(es)</b>			
Not regulated	Not regulated	Not regulated	Not regulated
<b>14.4. Packing group</b>			
Not regulated	Not regulated	Not regulated	Not regulated
<b>14.5. Environmental hazards</b>			
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. Transport in bulk according to Annex II of Marpol and the IBC Code

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

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

##### 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:

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830.

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

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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.

SDS EU (REACH Annex II)

*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*