

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

#### 1.1. Product identifier

Product form : Mixture  
Trade name : RESIN-GIPS PLUS  
Product code : 1108

#### 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](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

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

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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<br>EC-No.: 600-067-1<br>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".

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### 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 <sup>3</sup> (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.

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### 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  | : (Dependent on composition). |
| 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               |

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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

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### 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           |
|---|---------------|---------------|---------------|
| <b>14.1. UN number or ID 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  |               |               |               |

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### 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.

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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.