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## TECHNICAL FILE SILICONE FRESCO

### 1- Product Identification

Commercial Name : Silicone Fresco  
Product Description : Medical grade silicone to make medical Orthosis  
Reference : F-01923

#### Manufacturer:

Fresco International 2005 S.A.  
Sicilia 143, Barcelona (ESPAÑA)  
Telephone: +34 93 2314812

#### Product example:



#### Description:

Poly-condensation medium hardness silicone specially designed for its use in Podiatry. It is indicated to make both palliative and corrective orthosis. Easy to use its medical oils hydrate the skin, softening and helping regenerate the hyperkeratotic areas. It hardens with either liquid or paste catalyst. To achieve different hardness, it can be mixed with other poly-condensation silicones of the Fresco range. Moisten your fingers with water if the silicone paste adheres to the fingers when handling. The finished orthosis is washable and reusable. Professional use only.

## 2- Components Information

Color : Pink  
 Aspect : Semi-Rigid Paste  
 Solubility : Insoluble in water, easily separable by filtration.

## 3- Chemical Composition

The FRESCO Silicones are composed of:

- Base: Mixed of Polydimethylsiloxane and Silica. Elements composed basically by Silicone Elastomers, Medicinal White Oils, Silicone Oils and Silicone Pigment Paste, that vulcanize at room temperature with the addition of an external catalyst.

Boiling Point	: -
Flash Point	: > 200°C
Ignition Temperature	: > 450°C
Density	: 1.09 gr. / cm <sup>3</sup> a 20°C
Stretching	: 245%
100% modulus (Mpa)	: 0.56
Split Resistance (KN / m)	: 5.2
Breaking Strength MPa	: 1.4
Solubility in Water	: Practically Insoluble
Index Ph	: -
Hardness A	: 14-16

## 4- Hazard Identification

The product is not hazardous to health in normal handling. Keep out of reach of children. Do not use on open wounds. Should any irritation occur, seek to a medical specialist.

The product has been used for many years in several countries around the world, and until the date has found no cases of irritation or other skin problems.

### 4.1 - Norms

Marked (UE)

Phrases of Risk:

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Phrases of Security:

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### 4.2 - Additional norms:

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## 5 - Expiration Date and Lot Number

5.1 Date of Expiration: If the product is used and stored under appropriate conditions as specified in point No. 9, the life of the product may be more than 5 years. Sun exposure can vary its original color. When the jar has been left stored for more than a year without using it, the oil in the silicone might come to the top of

the jar and have a strong oily smell. When this happens, the product has not gone bad, simply, to make the smell disappear and its appearance as new, take all the silicone out, blend all the mass firmly until an even mass is achieved, and place it again in the jar.

5.2 Number of Batch: Each production batch is identified with Batch Number, which allows to recall the product from the market immediately in case of any possible problem. The Lot Number are provided on all invoices separately for each product line. The lot number is also added to each package of product, with a Tag.

#### 5.2.1 Production Flow Chart for Lot Number:

##### 1 - Subject:

Preparation of documentation in each production batch

##### 2 - Scope of Application:

The procedure described is applied to all the products manufactured by Fresco International 2005, S.A. at their installations at Parets del Vallès (Barcelona).

##### 3 - Procedure:

The preparation of documents is done by computer. Each time the worker begins to manufacture a batch of products, opening a production order, which has the following details:

- Batch / Lot Number
- Manufacturing Start Date
- Worker Name
- Materials to Use
- Amount to Craft

Once the batch has been completed, the worker closes the Order Manufacturing, adding:

- Amount Made
- Completion Date of Manufacture
- Storage placement

Then, label is printed for each carton with the following information:

- Lot Number
- Quantity per carton
- Date of Manufacture

The lot number is stored in the computer files of the company, and appears on the customer invoice for future control, if needed.

## 6 - Emergency and First Aid Procedures

- Inhalation: No special requirements
- Skin Contact: Product is used in direct contact with skin. We recommend not using the product more than 14 to 16 hours a day, to allow perspiration from the skin.
- Eye Contact: Wash with fresh water. If irritation persists, seek medical specialist.
- Ingestion: Medical oils are not toxic, but if swallowed, we recommend induce the vomiting and get medical advice.

- Health Additional Information: Not identified so far.

## 7 - Measures Anti-Flammable

- Provide adequate and regular fire extinguishers, fire can be controlled with sand, foam, carbon dioxide.
- Specific hazards may occur because of mixing and combustion of chemicals or gases.
- Use Special Protective Equipment for Fire Fighting

## 8 - Measures to Be Taken in Case of Accident Rand

Preventive Measures for Persons:

Special measures are not necessary.

Measures for Environmental Protection:

Observe the local standard.

Methods for collection / cleaning:

Collect with any mechanical method, and remove with appropriate methods.

## 9 - Handling and Storage

- Care of Handling: The product under normal use, is in direct contact with the skin, which should not take any special care, it is not even necessary to use gloves for handling.
- When this substance is spilled, increase the danger of slipping.
- Keep container closed
- When handling chemicals substances, must comply with general hygiene measures:
  - Respiratory Protection: Not required
  - Hand Protection: Not required
  - Eye Protection: Not required
- Storage Temperature: Room Temperature. Do not store at temperatures higher than 60 ° C, its shape may vary.
- Transport Temperature: Room Temperature. It should not be transported at higher temperatures of 60 ° C.
- Viscosity: Semi-Rigid
- Transport pressure: Atmospheric pressure.
- Electrostatic Accumulation Hazard: Not applicable
- Transport Containers: Plastic Bottles
- Adequate Cover: Plastic.
- Storage: Store in a dry place, Cool and aired place, and avoid contact with sunlight.
- Care after handling: No need to take any special care, after handling the product.
- Other Requirements: Not Applicable.

## 10- Transport:

- Air Transport: Not classified as Dangerous Goods.  
Applicable Standard: ICAO-TI / IATA-DGR
- Fluvial Transport: Not classified as Dangerous Goods.  
Applicable Standard: GGVBinsch / ADNR
- Maritime Transport: Not classified as Dangerous Goods.

Applicable Standard: GGVSea / IMDG-Code

- Land Transport: Not classified as Dangerous Goods.  
Applicable Standard: GGVS / ADR y GGVE / RID
  - Road GGVS / ADR
  - Railroad GGVE / RID

### 11- Individual Protection Control

No specific care is needed under normal use.

### 12- Physical and Chemical Characteristics

State at 20°C : Semi-Rigid  
Color : Pink  
Odor : Slightly Oily  
Density : 1.09 gr. / cm<sup>3</sup> at 20°C  
Hardness (Shore A) : 14-16

### 13 - Toxicological Information:

Effects after Prolonged Exposure: Not found.

#### **Carcinogenic effects:**

No effect reported by governmental authorities and agencies.

#### **Reproductive toxicity:**

No effect reported by governmental authorities and agencies.

### 14 - Ecological Information:

- No Pollutant Production.
- Product Non-Biodegradable
- Bioaccumulation Improbable

A proper disposal, through incineration, using a hazardous waste incinerator. Smaller quantities can be incinerated in an incinerator for household waste, in compliance with local codes. Household garbage can be deposited along with it, in compliance with local rules, after possibly having been compacted.

To empty the containers completely use a spatula. If packaging is reused, it is done at the users own risk and should observe local regulations.

### 15 - Packing Information:

Packaged in Plastic jars, in quantities of 500 gr. Containers placed in larger cardboard boxes for safe handling and transport.

### 16 - Regulatory Information:

The product is a Medical Article Class I, in accordance with Annex VII of the Directive EC 93/42/EC.

**17 - Other Data:**

The information provided should be regarded as a description of the relevant requirements of the safety of our product, not a legal warranty and does not replace the work of a professional healthcare practitioner, place a query to Fresco International 2005 S.A. in case of doubts.

Fresco International 2005 S.A., does not accept responsibility for misuse of the manufactured products, or if used for a different activity, the conditions of its use are not under our control.

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**Updated 01/04/2020**  
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