



# Liquid catalyst - Reaktol

## REF: F-01908



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**INDEX**

1.	DEVICE DESCRIPTION.....	11
2.	INTENDED PURPOSE .....	11
3.	INTENDED USERS.....	11
4.	MODE OF ACTION.....	11
5.	INSTRUCTIONS FOR USE.....	11
6.	END OF LIFE DISPOSAL.....	11
7.	WARNINGS AND PRECAUTIONS .....	11
8.	DEVICE COMPOSITION.....	11
8.1.	Raw Material.....	11
8.2.	Hazardous ingredients.....	11
8.3.	Biocompatibility tests .....	12
8.4.	Physical and chemical characteristics.....	12
9.	DEVICE VARIANTS, DIMENSIONS AND PACKAGING.....	12
9.1	PACKAGING MATERIAL SPECIFICATIONS .....	12
9.2	SÍMBOLOS .....	12
9.3	BATCH NUMBER.....	13
9.4	EXPIRY DATE .....	13
10.	PAO (PERIOD AFTER OPENING) .....	13
11.	STORAGE .....	13
12.	TRANSPORTATION .....	13
13.	HANDLING .....	13
15.	EMERGENCY AND FIRST AID PROCEDURES .....	14
16.	TOXICOLOGICAL INFORMATION.....	15
17.	MEASURES TO FOLLOW IN CASE OF A FORTUITE ACCIDENT .....	15
18.	IMPORTANT INFORMATION .....	16
19.	DOCUMENT VERSION CONTROL.....	16

**1. DEVICE DESCRIPTION**

Liquid catalyst.

**2. INTENDED PURPOSE**

Specially designed for use in podiatry, it is indicated for preparing palliative or corrective orthoses for its vulcanization.

**3. INTENDED USERS**

Intended professional use.

**4. MODE OF ACTION**

It is mixed with podiatric polycondensation silicones and solidifies them in the orthosis manufacturing process.

**5. INSTRUCTIONS FOR USE**

Mix together with the silicone until a uniform paste is obtained (for 30-60 seconds). It has to be mixed in a maximum ratio of 1 drop of catalyst per gram of product. The mixture needs approximately 5 minutes to solidify.

**6. END OF LIFE DISPOSAL**

Advice on disposal: Do not allow to enter surface water or drains. Do not allow to enter soil/subsoil. Dispose of waste in accordance with applicable legislation.

Contaminated packaging: This material and its packaging should be disposed of as hazardous waste. Handle contaminated packaging in the same manner as the substance itself.

**7. WARNINGS AND PRECAUTIONS**

Precautionary statements:

P201	Obtain special instructions before use.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P305+P351+P338	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313	If exposed or concerned: Get medical advice/attention.
P310	Immediately call a poison centre/doctor.
P501	Dispose of contents/ container in accordance with local and national regulations.

**8. DEVICE COMPOSITION****8.1. Raw Material**

Silicon-tin-compound with auxiliary matters.

**8.2. Hazardous ingredients**

CAS No	Chemical name	EC No	REACH No	Classific. Reg. (EC) No. 1272/2008
93922-42-9	Alkylstannonic siloxanes (>80%)	300-344-4	01-2119560586-30	Flam. Liq. 3, Muta. 2, Repr. 1, Acute Tox. 4, Eye Dam. 1, Stot RE 1, Aquatic Chronic 3, H226 H341 H360F H332 H302 H318 H372 H412

### 8.3. Biocompatibility tests

Testing has been conducted in accordance with "ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a risk management process".

The specific biocompatibility test conducted are the following:

1. Cytotoxicity.
2. Intracutaneous.
3. Skin sensitization.

### 8.4. Physical and chemical characteristics

Boiling point	>100°C
Flash point	>100°C
Ignition temperatura	>300°C
Vapour pressure	<1hPa at 20°C
Density	1,0g/cm <sup>3</sup> at 20°C
Dynamic Viscosity	<80mPA.s at 23°C
Water solubility	insoluble

## 9. DEVICE VARIANTS, DIMENSIONS AND PACKAGING.

Referencias	Cantidad (ml)	Cantidades	Envase
F-01908-00	20	1	Plastic
F-01908-01	20	1	Recipiente plástico sin serigrafiar
F-01908-10	10	1	Recipiente plástico

### 9.1 PACKAGING MATERIAL SPECIFICATIONS

	Pap: Plastic (PP)
Label	

All materials are 100% recyclable

### 9.2 SÍMBOLOS



### Avisos de peligrosidad:

H302+H332	Harmful if swallowed or if inhaled.
H319	Causes serious eye irritation.
H341	Suspected of causing genetic defects.
H360F	May damage fertility.
H372	Cause damage to organs (Thymus) through prolonged or repeated exposure if swallowed.
H412	Harmful to aquatic life with long lasting effects.

### 9.3 BATCH NUMBER

**LOT**

**YYXXXX**

6 digits

**YY**

Year of production

**XXXX**

Automatic and contiguous, system generated.

### 9.4 EXPIRY DATE



**YYYY-MM**

6 digits

**YYYY**

Year

**MM**

Month

2 years after manufacturing.

### 10. PAO (PERIOD AFTER OPENING)

Does not apply. There is no caducity or changes on the product composition due to open the packaging.

### 11. STORAGE

Requirements for storerooms and containers: Keep container tightly closed. Keep under lock and key. Store in a place accessible only to authorized persons. Provide adequate ventilation and local exhaust at critical locations.

Information about storage compatibility: Do not store with strong oxidizing substances.

Further information: Store only in the original container in a cool, dry and well-ventilated place away from foodstuffs.

### 12. TRANSPORTATION

It is not considered a hazardous substance in terms of transport regulation.

Temperature: Room temperature.

Pressure: Atmospheric

### 13. HANDLING

Advice on safe handling: If handling in the open, use local exhaust ventilation devices. Do not breathe fumes/fumes/vapours/aerosols.

### 14. CONTROL OF INDIVIDUAL PROTECTION

**Appropriate engineering controls**

If handled in the open, use local exhaust ventilation devices. Do not breathe gas/fumes/vapours/spume/spray.

**Skin protection**

The product is used on direct contact with the skin.

**Respiratory protection**

In case of inadequate ventilation, wear respiratory protection.

**15. EMERGENCY AND FIRST AID PROCEDURES****General Information**

First aid: Pay attention to self-protection. Remove the affected person from the danger zone and lay him/her down.

**In case of inhalation**

Provide fresh air. In case of doubt or if symptoms are observed, consult a doctor.

**In case of contact with eyes**

In case of contact with eyes, rinse immediately with plenty of running water for 10 to 15 minutes holding the eyelids apart and consult an ophthalmologist.

**In case of ingestion**

Rinse mouth immediately and drink plenty of water. Drink water in small sips (dilution effect). Seek medical attention immediately. Do not induce vomiting. In case of spontaneous vomiting, make sure that the vomit comes out unhindered (danger of asphyxia).

**Anti-inflammatory measures**

Non-flammable, but burns. Products of combustion may include carbon monoxide and carbon dioxide.

**Extinguishing measures**

Suppress gases/vapours/mists with water spray. Collect contaminated extinguishing water separately. Do not allow to enter drains or surface water.

**Risk of fire and explosion**

None identified

**Stability and reactivity**

No dangerous reaction if handled and stored according to regulations.

The product is stable when stored at normal room temperature.

Reacts with: strong oxidizing agents.

High temperatures promote the formation of flammable vapors, so do not expose the product to high temperatures.

No dangerous decomposition products are known.