

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

- **1.1 Product identifier**
- **Trade name: SILICON FILM CATALIZZATORE (A) - SILICON FILM BASE (B)**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Life cycle stages PW** Widespread use by professional workers
- **Application of the substance / the mixture** Material for dental use
- **Uses advised against** Any use other than those identified is not recommended.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Dental Manufacturing S.p.a.
Via Cà Mignola Nuova, 1699
45021 - Badia Polesine (RO) - Italy
Tel. +39 0425 51628 - Fax +39 0425 590156
- **Further information obtainable from:** info@ruthinium.it
- **1.4 Emergency telephone number:**
Dental Manufacturing S.p.a. - Tel. +39 0425 51628 (Office Hours)
Centro Antiveleni di Milano 02 66101029 (CAV Ospedale Niguarda Ca' Granda -Milano)
Centro Antiveleni di Pavia 0382 24444 (CAV IRCCS Fondazione Maugeri - Pavia)
Centro Antiveleni di Bergamo 800 883300 (CAV Ospedali Riuniti - Bergamo)
Centro Antiveleni di Firenze 055 7947819 (CAV Ospedale Careggi - Firenze)
Centro Antiveleni di Roma 06 3054343 (CAV Policlinico Gemelli - Roma)
Centro Antiveleni di Roma 06 49978000 (CAV Policlinico Umberto I - Roma)
Centro Antiveleni di Napoli 081 7472870 (CAV Ospedale Cardarelli - Napoli)
Centro Antiveleni di Foggia 0881 732326 (CAV Ospedale Univ. - Foggia)
Centro Antiveleni di Roma 06 68593726 (CAV Osp. Pediatrico Bambino Gesù - Roma)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified, according to the CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:**
preparation based on poly (dimethylsiloxane) derivatives, fillers and platinum complexes
- **Dangerous components:**
absence of hazardous ingredients in accordance with the applicable regulations
- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 17.01.2019

Version number 1

Revision: 17.01.2019

Trade name: SILICON FILM CATALIZZATORE (A) - SILICON FILM BASE (B)

(Contd. of page 1)

- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**
Rinse with warm water.
Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:**
Rinse your mouth well
In case of complaints seek medical advice
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
Use fire extinguishing methods suitable to surrounding conditions.
CO₂, powder or water spray. Fight larger fires with water spray.
- **For safety reasons unsuitable extinguishing agents:** None in particular
- **5.2 Special hazards arising from the substance or mixture**
No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:**
See Section 8 for information on personal protection equipment.
See Section 8 for information on personal protection equipment.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
You should follow the usual precautions for handling chemical products
No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

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(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 17.01.2019

Version number 1

Revision: 17.01.2019

Trade name: SILICON FILM CATALIZZATORE (A) - SILICON FILM BASE (B)

(Contd. of page 2)

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:** Not required.
- **Material of gloves:** Void
- **Penetration time of glove material:** Void
- **Eye protection:** Goggles recommended during refilling

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Fluid
Colour:	Colourless
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **pH-value:** Not applicable
- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	100 °C
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not applicable.
- **Auto-ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.
- **Vapour pressure:** Not determined.
- **Density at 20 °C:** 1.30 g/cm³
- **Relative density:** Not determined.
- **Vapour density:** Not determined.
- **Evaporation rate:** Not determined.
- **Solubility in / Miscibility with water:** Not miscible or difficult to mix.
- **Partition coefficient: n-octanol/water:** Not determined.
- **Viscosity:**

Dynamic:	Not determined.
Kinematic:	Not determined.

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

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Revision: 17.01.2019

Trade name: SILICON FILM CATALIZZATORE (A) - SILICON FILM BASE (B)

(Contd. of page 3)

· 9.2 Other information

No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** Excessive variations in temperature, below 0 ° C and above 40 ° C
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **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.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** Non significant accumulation in organisms
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Do not discard the product or its packaging. Do not empty into drains. Recycle the product. When recycling is not possible, dispose through an authorized company in compliance with the local or national regulations. The assignment of the waste code is the user's responsibility, after determining the properties of the waste and the process generating it and after discussing it with the authorities responsible for disposal.

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 17.01.2019

Version number 1

Revision: 17.01.2019

Trade name: SILICON FILM CATALIZZATORE (A) - SILICON FILM BASE (B)

(Contd. of page 4)

- **Uncleaned packaging:**

- **Recommendation:**

Empty the containers before disposal. Do not reuse the emptied containers. Send the empty containers to recycling or to an authorized company in compliance with local and national regulations.

SECTION 14: Transport information

- **14.1 UN-Number**

- **ADR, ADN, IMDG, IATA** Void

- **14.2 UN proper shipping name**

- **ADR, ADN, IMDG, IATA** Void

- **14.3 Transport hazard class(es)**

- **ADR, ADN, IMDG, IATA**

- **Class** Void

- **14.4 Packing group**

- **ADR, IMDG, IATA** Void

- **14.5 Environmental hazards:**

- **Marine pollutant:** No

- **14.6 Special precautions for user**

Not applicable.

- **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable.

- **Transport/Additional information:**

Not dangerous according to the above specifications.

- **UN "Model Regulation":**

Void

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

Safety data sheet prepared in accordance with Regulation 1907/2006/EC Article 31, Regulation (EU) No 830/2015 as subsequent amendments.

- **Labelling according to Regulation (EC) No 1272/2008 GHS label elements**

- **Directive 2012/18/EU**

- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

- **Classification according to Regulation (EC) No 1272/2008**

As required by Regulation 1272/2008/CE art. 9, the classification of this compound is based on the calculation method taken from the data of the single substances therein and from the experimental data of this compound where available (viewable in sections 9, 11 and 12 in this document).

(Contd. on page 6)

Safety data sheet
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Trade name: SILICON FILM CATALIZZATORE (A) - SILICON FILM BASE (B)

(Contd. of page 5)

Procedure used for the classification of the mixture

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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