

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

- **1.1 Product identifier**
- **Trade name: ACTIVATOR PASTE**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Life cycle stages PW** Widespread use by professional workers
- **Sector of Use**  
SU22 Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
- **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**



Skin Irrit. 2 H315 Causes skin irritation.  
 Eye Irrit. 2 H319 Causes serious eye irritation.  
 STOT SE 3 H335 May cause respiratory irritation.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



- **Signal word** Warning
- **Hazard-determining components of labelling:**  
tetraethyl silicate
- **Hazard statements**  
H315 Causes skin irritation.

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H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

- **Precautionary statements**

P280 Wear protective gloves / eye protection / face protection.

P302+P352 IF ON SKIN: Wash with plenty of water.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

- **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:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 78-10-4 EINECS: 201-083-8 Reg.nr.: 01-2119496195-28	tetraethyl silicate ⚠ Flam. Liq. 3, H226; ⚠ Acute Tox. 4, H332; Eye Irrit. 2, H319; STOT SE 3, H335	25-40%
CAS: 23850-94-4	butyltris[(2-ethyl-1-oxohexyl)oxy]stannane ⚠ Skin Irrit. 2, H315; Aquatic Chronic 4, H413	15-25%

- **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:**

Rescue workers must wear the protective equipment described in section 8.2 of this safety data sheet.

- **After inhalation:** Supply fresh air; consult doctor in case of complaints.

- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

- **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- **After swallowing:**

Rinse out mouth and then drink plenty of water.

Do not induce vomiting; call for medical help immediately.

- **4.2 Most important symptoms and effects, both acute and delayed**

Skin: irritation

Eyes: irritation

- **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.

CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- **For safety reasons unsuitable extinguishing agents:** Water with full jet

- **5.2 Special hazards arising from the substance or mixture**

No further relevant information available.

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- **5.3 Advice for firefighters**
- **Protective equipment:**  
Mouth respiratory protective device.  
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**  
Wear protective clothing.  
See Section 8 for information on personal protection equipment.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Dispose contaminated material as waste according to item 13.  
Ensure adequate ventilation.
- **6.4 Reference to other sections**  
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  
Ensure good ventilation/exhaustion at the workplace.  
Keep away from heat and direct sunlight.
- **Information about fire - and explosion protection:**  
Emergency cooling must be available in case of nearby fire.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

### 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:**

<b>78-10-4 tetraethyl silicate</b>
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WEL Long-term value: 44 mg/m <sup>3</sup> , 5 ppm
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- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes and skin.
- **Respiratory protection:** Suitable respiratory protective device recommended.

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- **Protection of hands:**



Protective gloves

Only use EN 374-3 certified protective gloves against chemical agents.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

Neoprene gloves

Nitrile rubber, NBR

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Recommended thickness of the material:  $\geq 0.2$  mm

- **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Value for the permeation: Level 2/3

- **Eye protection:**



Tightly sealed goggles

### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

**Form:** Pasty

**Colour:** Dark blue

- **Odour:** Characteristic

- **Odour threshold:** Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

**Melting point/freezing point:** Undetermined.

**Initial boiling point and boiling range:** Undetermined.

- **Flash point:** 62 °C

- **Flammability (solid, gas):** Not determined.

- **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 at 20 °C:** 23 hPa

- **Density at 20 °C:** 0.98 g/cm<sup>3</sup>

- **Relative density** Not determined.

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|---|--|
| <ul style="list-style-type: none"> <li>· <b>Vapour density</b></li> <li>· <b>Evaporation rate</b></li> </ul>  | <ul style="list-style-type: none"> <li>Not applicable.</li> <li>Not applicable.</li> </ul>   |
| <ul style="list-style-type: none"> <li>· <b>Solubility in / Miscibility with water:</b></li> </ul>  | <ul style="list-style-type: none"> <li>Insoluble.</li> </ul>   |
| <ul style="list-style-type: none"> <li>· <b>Partition coefficient: n-octanol/water:</b></li> </ul>  | <ul style="list-style-type: none"> <li>Not determined.</li> </ul>  |
| <ul style="list-style-type: none"> <li>· <b>Viscosity:</b></li> <li style="padding-left: 20px;">Dynamic:</li> <li style="padding-left: 20px;">Kinematic:</li> <li>· <b>9.2 Other information</b></li> </ul> | <ul style="list-style-type: none"> <li>Not applicable.</li> <li>Not applicable.</li> <li>No further relevant information available.</li> </ul> |

### 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:** Avoid contact with acids and oxidants.
- **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.

- **LD/LC50 values relevant for classification:**

#### 78-10-4 tetraethyl silicate

Oral	LD50	6,270 mg/kg (rat)
Dermal	LD50	5,878 mg/kg (rabbit)
Inhalative	LC50/4 h	10 mg/l (rat) (OECD TG403)

- **Primary irritant effect:**
- **Skin corrosion/irritation**  
Causes skin irritation.
- **Serious eye damage/irritation**  
Causes serious eye irritation.
- **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**  
May cause respiratory irritation.
- **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:**

#### 78-10-4 tetraethyl silicate

CL50	>245 mg/l (fish) (OECD TG 203 esposizione 96 h)
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EC50	100 mg/l (algae) (OECD TG 201 Esposizione 72h)
	>75 mg/l (daphnia) (OECD TG 202 esposizione 48 h)
NOEC	>245 mg/l (fish) (OECD TG 203)

- **12.2 Persistence and degradability** Easily biodegradable
- **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.
- **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.
- **Recommended cleansing agents:** Water.

### SECTION 14: Transport information

- |   |                 |
|---|-----------------|
| <ul style="list-style-type: none"> <li>· <b>14.1 UN-Number</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>   | Void            |
| <ul style="list-style-type: none"> <li>· <b>14.2 UN proper shipping name</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>                                 | Void            |
| <ul style="list-style-type: none"> <li>· <b>14.3 Transport hazard class(es)</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | Void            |
| <ul style="list-style-type: none"> <li>· <b>14.4 Packing group</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>   | Void            |
| <ul style="list-style-type: none"> <li>· <b>14.5 Environmental hazards:</b></li> <li>· <b>Marine pollutant:</b></li> </ul>                                | No              |
| <ul style="list-style-type: none"> <li>· <b>14.6 Special precautions for user</b></li> </ul>  | Not applicable. |
| <ul style="list-style-type: none"> <li>· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b></li> </ul>                        | Not applicable. |

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<b>· UN "Model Regulation":</b>	Void
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### 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.

- **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.

**· Relevant phrases**

H226 Flammable liquid and vapour.  
 H315 Causes skin irritation.  
 H319 Causes serious eye irritation.  
 H332 Harmful if inhaled.  
 H335 May cause respiratory irritation.  
 H413 May cause long lasting harmful effects to aquatic life.

**· 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).

Procedure used for the classification of the mixture

Skin Irrit. 2, H315 - Calculation method

Eye Irrit. 2, H319 - Calculation method

STOT SE 3, H335 - Calculation method

**· 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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 3: Flammable liquids – Category 3

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4