

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 04.04.2024

Version number 4 (replaces version 3)

Revision: 04.04.2024

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

- **1.1 Product identifier**
- **Trade name: ACTIVATOR PASTE**
- **UFI: 1S00-G0PQ-R00V-M83U**
- **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)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS07

- 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**



GHS07

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

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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.

- **Labelling of packages where the contents do not exceed 125 ml**
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**
tetraethyl silicate
- **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 Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 78-10-4 EINECS: 201-083-8 Index number: 014-005-00-0 Reg.nr.: 01-2119496195-28	tetraethyl silicate ⚠ Flam. Liq. 3, H226; ⚠ Acute Tox. 4, H332; Eye Irrit. 2, H319; STOT SE 3, H335 ATE: LC50/4 h inhalative: 10 mg/l	25-35%
CAS: 23850-94-4 EINECS: 245-912-1 Reg.nr.: 01-2120771041-66-	butyltris[(2-ethyl-1-oxohexyl)oxy]stannane ⚠ Skin Irrit. 2, H315; Aquatic Chronic 4, H413	15-21%

- **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.
- **IF INHALATED:** 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.
If ingested do not induce vomiting, seek medical assistance showing the safety data sheet or the hazard label
- **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.

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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:** Water with full jet
- **5.2 Special hazards arising from the substance or mixture**
No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:**
As in any fire, wear self-contained breathing apparatus and appropriate protective clothing including gloves and eye / face protection.
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.
Wear protective equipment. Keep unprotected persons away.
- **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 section 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
Avoid contact with eyes and skin.
- **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 data; see section 1.2.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

CAS: 78-10-4 tetraethyl silicate (25-40%)

OEL	Long-term value: 44 mg/m ³ , 5 ppm
IOELV	

- **Regulatory information** OEL: 2021 CoP for the Safety, Health and Welfare at Work

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- **DNELs**

CAS: 78-10-4 tetraethyl silicate

Dermal	Long term, systemic effect	12.1 mg/kg bw/day (professional workers)
Inhalative	Long term, systemic effect	85 mg/m ³ (professional workers)

- **PNECs**

CAS: 78-10-4 tetraethyl silicate

PNEC	0.18 mg/kg /peso bagna (fresh water sediments)
	0.018 mg/kg /peso bagn (marine water sediments)
PNEC	0.192 mg/l (freshwater)
	10 mg/l (intermittent releases)
	0.0192 mg/l (marine water)
	4,000 mg/l (sewage treatment plant)

- **Additional information:** The lists valid during the making were used as basis.

- **8.2 Exposure controls**

- **Appropriate engineering controls** No further data; see section 7.

- **Individual protection measures, such as personal protective equipment**

- **General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

- **Respiratory protection:**

Suitable respiratory protective device recommended.

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

- **Hand protection**



Protective gloves

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.

- **Penetration time of glove material**

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

Breakthrough time: > = 480 min - Material thickness: > = 0.7 mm

Breakthrough time: > = 60 min - Material thickness: > = 0.5 mm

Breakthrough time: > = 30 min - Material thickness: > = 0.2 mm

- **Eye/face protection**



Tightly sealed goggles

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SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Physical state	Solid
· Colour:	Blue
· Odour:	Characteristic
· Odour threshold:	Not determined.
· Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling point and boiling range	Undetermined.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	>62 °C
· pH	Not applicable.
· Viscosity:	
· Kinematic viscosity	Not applicable.
· Dynamic:	Not applicable.
· Solubility	
· water:	Insoluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure at 20 °C:	23 hPa
· Density and/or relative density	
· Density at 20 °C:	0.98 g/cm ³
· Relative density	Not determined.
· Vapour density	Not applicable.
· Particle characteristics	
See section 3.	

· 9.2 Other information

· Appearance:	
· Form:	Pasty
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Evaporation rate	Not applicable.

· Information with regard to physical hazard classes

· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void

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- | | |
|----------------------------------|------|
| · Corrosive to metals | Void |
| · Desensitised explosives | Void |

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No hazardous reactions when stored and handled according to instructions
- **10.2 Chemical stability** The product is stable under normal conditions of use and storage
- **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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

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

CAS: 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)

- **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.
- **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.
- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

- **12.1 Toxicity**

- **Aquatic toxicity:**

CAS: 78-10-4 tetraethyl silicate

CL50	>245 mg/l (fish) (OECD TG 203 esposizione 96 h)
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** No further relevant information available.
- **12.3 Bioaccumulative potential** Non significant accumulation in organisms
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **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.

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.

SECTION 14: Transport information

- | | |
|---|--|
| <ul style="list-style-type: none"> · 14.1 UN number or ID number · ADR, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · 14.2 UN proper shipping name · ADR, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class | Void |
| <ul style="list-style-type: none"> · 14.4 Packing group · ADR, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · 14.5 Environmental hazards: · Marine pollutant: | No |
| <ul style="list-style-type: none"> · 14.6 Special precautions for user | Not applicable. |
| <ul style="list-style-type: none"> · 14.7 Maritime transport in bulk according to IMO instruments | Not applicable. |
| <ul style="list-style-type: none"> · Transport/Additional information: | Not dangerous according to the above specifications. |
| <ul style="list-style-type: none"> · 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 878/2020 as subsequent amendments.

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- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

- **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

- **REGULATION (EU) 2019/1148**

- **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

- **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

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.

- **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

- **Date of previous version:** 04.04.2024

- **Version number of previous version:** 3

- **Abbreviations and acronyms:**

ADR: Accord relatif au transport international 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)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

ATE: Acute toxicity estimate values

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

- *** Data compared to the previous version altered.**