



**Safety data sheet
according to 1907/2006/EC, Article 31**

Printing date 03.08.2022

Version number 5 (replaces version 4)

Revision: 03.08.2022

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

· **1.1 Product identifier**

· Trade name: **Activator Universal Plus Paste**

· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Application of the substance / the mixture** Activator for dental impression material

· **1.3 Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 4372522

· **Informing department:** E-Mail: msds@kulzer-dental.com

· **1.4 Emergency telephone number:** Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**

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

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Skin Sens. 1B H317 May cause an allergic skin reaction.

· **2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the GB CLP regulation.

· **Hazard pictograms**



GHS02 GHS07

· **Signal word** Danger

· **Hazard-determining components of labelling:**

Reaction product of tetraethoxysilane, alkylated polysilicate, dioctyltin oxide and benzoic acid

· **Hazard statements**

H225 Highly flammable liquid and vapour.

H317 May cause an allergic skin reaction.

· **Precautionary statements**

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P233 Keep container tightly closed.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

· **2.3 Other hazards -**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**

· **Description:** -

· **Dangerous components:**

ELINCS: 477-470-2 Reg.nr.: 01-0000019944-59-XXXX	Reaction product of tetraethoxysilane, alkylated polysilicate, dioctyltin oxide and benzoic acid Flam. Liq. 2, H225 Skin Sens. 1B, H317	25-50%
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· **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**

· **After inhalation** Supply fresh air; consult doctor in case of symptoms.

· **After skin contact** If skin irritation continues, consult a doctor.

· **After eye contact**

Rinse opened eye for several minutes under running water. Then consult doctor.

· **After swallowing**

Rinse out mouth and then drink plenty of water.

In case of persistent symptoms consult doctor.

· **4.2 Most important symptoms and effects, both acute and delayed** Allergic reactions

· **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**

Alcohol-resistant foam

CO₂, sand, extinguishing powder. Do not use water.

· **For safety reasons unsuitable extinguishing agents** Water with a full water jet.

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

Can form explosive gas-air mixtures.

Carbon monoxide (CO)

Carbon dioxide (CO₂)

Formation of toxic gases is possible during heating or in case of fire.

· **5.3 Advice for firefighters**

· **Protective equipment:** No special measures required.

· **Additional information** -

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures**

Wear protective equipment. Keep unprotected persons away.

· **6.2 Environmental precautions:**

Do not allow to enter drainage system, surface or ground water.

Do not allow to enter the ground/soil.

Prevent material from reaching sewage system, holes and cellars.

· **6.3 Methods and material for containment and cleaning up:**

Collect mechanically.

Send for recovery or disposal in suitable containers.

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· **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 information on disposal.

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SECTION 7: Handling and storage

· **7.1 Precautions for safe handling**

Please observe the additional instructions in the product's instructions for use.

Keep containers tightly sealed.

Keep away from heat and direct sunlight.

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

· **Information about protection against explosions and fires:**

Keep ignition sources away - Do not smoke.

Protect from heat.

Protect against electrostatic charges.

· **7.2 Conditions for safe storage, including any incompatibilities**

· **Storage**

· **Requirements to be met by storerooms and containers:** No special requirements.

· **Information about storage in one common storage facility:** Not required.

· **Further information about storage conditions:**

Store under dry conditions.

Store container in a well ventilated position.

Protect from heat and direct sunlight.

· **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**

· **Components with critical 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.

Not required.

· **Additional information:** The lists that were valid during the compilation were used as basis.

· **8.2 Exposure controls**

· **Appropriate engineering controls** No further data; see item 7.

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

· **General protective and hygienic measures**

Instantly remove any soiled and impregnated garments.

Wash hands during breaks and at the end of the work.

· **Breathing equipment:** Not required.

· **Hand protection**

Impervious gloves

If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.

Check protective gloves prior to each use for their proper condition.

recommended

· **Material of gloves**

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

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calculated in advance and has therefore to be checked prior to the application.

- **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.
- **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**
Butyl rubber, BR
Nitrile rubber, NBR
- **Eye/face protection** Tightly sealed safety glasses.
- **Body protection:**
Protective work clothing.
Light weight protective clothing

SECTION 9: Physical and chemical properties

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

· **General Information**

- **Physical state** Fluid
- **Colour:** Red
- **Smell:** Aromatic
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** Not determined
- **Boiling point or initial boiling point and boiling range** $\geq 300\text{ °C}$ (8009-03-8 Petrolatum)
- **Flammability** Not applicable.
- **Lower and upper explosion limit**
 - **Lower:** 1.3 Vol %
 - **Upper:** 23 Vol %
- **Flash point:** 21.1 °C (Reaction product of tetraethoxysilane, alkylated polysilicate, dioctyltin oxide and benzoic acid)
- **Ignition temperature:** 234 °C
- **Decomposition temperature:** Not determined.

· **SADT**

- **pH** Not determined.
- **Viscosity:**
 - **Kinematic viscosity** Not determined.
 - **dynamic:** Not determined.
- **Solubility**
 - **Water:** Not miscible or difficult to mix
- **Partition coefficient n-octanol/water (log value)** Not determined.
- **Steam pressure:** Not determined.
- **Density and/or relative density**
 - **Density at 20 °C** 1.15 g/cm³
 - **Relative density** Not determined.
 - **Vapour density** Not determined.

· **9.2 Other information**

No further relevant information available.

- **Appearance:**
- **Form:** Pasty

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· Important information on protection of health and environment, and on safety.

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|--------------------------------|--|
| · Self-inflammability: | Product is not selfigniting. |
| · Explosive properties: | Product is not explosive. However, formation of explosive air/vapour mixtures is possible. |
| · Solvent content: | |
| · Solids content: | 60.4 % |
| · Change in condition | |
| · Evaporation rate | Not determined. |

· Information with regard to physical hazard classes

- | | |
|--|-------------------------------------|
| · Explosives | Void |
| · Flammable gases | Void |
| · Aerosols | Void |
| · Oxidising gases | Void |
| · Gases under pressure | Void |
| · Flammable liquids | Highly flammable liquid and vapour. |
| · 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 |
| · Corrosive to metals | Void |
| · Desensitised explosives | Void |

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
 - **Conditions to be avoided:** No decomposition if used and stored according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None
- **Additional information:** -

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 that are relevant for classification:

Reaction product of tetraethoxysilane, alkylated polysilicate, dioctyltin oxide and benzoic acid

Oral	LD50	>2,000 mg/kg (not defined)
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112945-52-5 Amorphous silica

Oral LD50 >5,000 mg/kg (rat) (OECD 401)

Dermal LD50 >5,000 mg/kg (rabbit)

- **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**
May cause an allergic skin reaction.
- **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.

· **Additional toxicological information:**

- Sensitisation Guinea-Pig Maximisation Test (OECD 406): positive

· **11.2 Information on other hazards**· **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information· **12.1 Toxicity**· **Aquatic toxicity:****Reaction product of tetraethoxysilane, alkylated polysilicate, dioctyltin oxide and benzoic acid**

EC50/72h >100 mg/l (algae)

EC50/48h >100 mg/l (daphnia) (OECD 201)

112945-52-5 Amorphous silica

LC50/96h >10,000 mg/l (fish) (OECD 203)

EC50 / 24h >1,000 mg/l (daphnia)

· **12.2 Persistence and degradability** No further relevant information available.· **12.3 Bioaccumulative potential** No further relevant information available.· **12.4 Mobility in soil** No further relevant information available.· **12.5 Results of PBT and vPvB assessment**· **PBT:** Not applicable.· **vPvB:** Not applicable.· **12.6 Endocrine disrupting properties**

For information on endocrine disrupting properties see section 11.

· **12.7 Other adverse effects**· **Additional ecological information:**

- **General notes:** Avoid transfer into the environment.

SECTION 13: Disposal considerations· **13.1 Waste treatment methods**· **Recommendation**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

Disposal must be made according to official regulations.

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· **Uncleaned packagings:**· **Recommendation:**

Disposal must be made according to official regulations.

Non contaminated packagings can be used for recycling.

SECTION 14: Transport information· **14.1 UN number or ID number**

· ADR, IMDG, IATA

UN1993

· **14.2 UN proper shipping name**

· ADR

1993 FLAMMABLE LIQUID, N.O.S., special provision 640D (Reaction product of tetraethoxysilane, alkylated polysilicate, dioctyltin oxide and benzoic acid)

· IMDG, IATA

FLAMMABLE LIQUID, N.O.S. (Reaction product of tetraethoxysilane, alkylated polysilicate, dioctyltin oxide and benzoic acid)

· **14.3 Transport hazard class(es)**

· ADR

· Class
· Label3 (F1) Flammable liquids.
3

· IMDG, IATA

· Class
· Label3 Flammable liquids.
3· **14.4 Packing group**

· ADR, IMDG, IATA

II

· **14.5 Environmental hazards:**

· Marine pollutant:

No

· **14.6 Special precautions for user**

· Kemler Number:

Warning: Flammable liquids.

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· EMS Number:

F-E, S-E

· Stowage Category

B

· **14.7 Maritime transport in bulk according to IMO instruments**

Not applicable.

· Transport/Additional information:

-

· ADR

· Limited quantities (LQ)

1L

· Excepted quantities (EQ)

Code: E2

Maximum net quantity per inner packaging:

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	30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category	2
· Tunnel restriction code	D/E
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· IMDG	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1993 FLAMMABLE LIQUID, N.O.S., SPECIAL PROVISION 640D (REACTION PRODUCT OF TETRAETHOXYSilANE, ALKYLATED POLYSILICATE, DIOCTYLtin OXIDE AND BENZOIC ACID), 3, II

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
 - **Directive 2012/18/EU**
 - **Named dangerous substances - ANNEX I** None of the ingredients is listed.
 - **Seveso category P5c** FLAMMABLE LIQUIDS
 - **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5,000 t
 - **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50,000 t
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**
 - H225 Highly flammable liquid and vapour.
 - H317 May cause an allergic skin reaction.
- **Abbreviations and acronyms:**
 - SADT: Self Accelerating Decomposition Temperature
 - 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)
 - LC50: Lethal concentration, 50 percent
 - LD50: Lethal dose, 50 percent
 - PBT: Persistent, Bioaccumulative and Toxic
 - vPvB: very Persistent and very Bioaccumulative
 - Flam. Liq. 2: Flammable liquids – Category 2
 - Skin Sens. 1B: Skin sensitisation – Category 1B
- *** Data compared to the previous version altered.**