



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

Printing date 06.04.2023

Version number 6 (replaces version 5)

Revision: 06.04.2023

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**

The product is not classified, according to the GB CLP regulation.

· **Additional information:**

Since the product is a medical device in the sense of Directive 93/42/EEC (MDD) or the Regulation (EU) 2017/745 (MDR), that is intended for the end user and is used invasively or with physical contact, it is exempted from the classification and labeling obligation according to Regulation (EC) 1272/2008.

· **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 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%

· **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.

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- **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.
- **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.
-

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.

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- **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 section 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 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

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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	≥300 °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)
· Auto-ignition temperature:	234 °C
· Decomposition temperature:	Not determined.
· SADT	
· pH	Not determined.
· Viscosity:	
· Kinematic viscosity	Not determined.
· Kinematic viscosity	
· dynamic:	Not determined.
· Solubility	
· Water:	Not miscible or difficult to mix
· Partition coefficient n-octanol/water (log value)	Not determined.
· Steam pressure:	Not determined.
· Vapour pressure:	
· Density and/or relative density	
· Density at 20 °C	1.15 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.

9.2 Other information

No further relevant information available.

Appearance:

· Form: Pasty

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

· 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

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· 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
· 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)
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Dermal	LD50	>5,000 mg/kg (rabbit)
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- **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.
- **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

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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.

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

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· **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**
· **Label**

3 (F1) Flammable liquids.
3

· **IMDG, IATA**



· **Class**
· **Label**

3 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:**
· **EMS Number:**
· **Stowage Category**

Warning: Flammable liquids.
33
F-E, S-E
B

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

Not applicable.

· **Transport/Additional information:**

-

· **ADR**

· **Limited quantities (LQ)**
· **Excepted quantities (EQ)**

1L
Code: E2
Maximum net quantity per inner packaging:
30 ml
Maximum net quantity per outer packaging:
500 ml
2
D/E

· **Transport category**
· **Tunnel restriction code**

· **IMDG**

· **Limited quantities (LQ)**
· **Excepted quantities (EQ)**

1L
Code: E2
Maximum net quantity per inner packaging:
30 ml
Maximum net quantity per outer packaging:

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500 ml

· **UN "Model Regulation":** UN 1993 FLAMMABLE LIQUID, N.O.S., SPECIAL PROVISION 640D (REACTION PRODUCT OF TETRAETHOXYSILANE, ALKYLATED POLYSILICATE, DIOCTYL TIN 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.**