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

Printing date 26.07.2021 Version number 5 Revision: 26.07.2021

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 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.

(Contd. on page 2)

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: 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.
· **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.

(Contd. on page 3)

(Contd. of page 2)

· **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**
· **Additional information about design of technical systems:** No further data; see item 7.
· **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**
· **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.
· **Protection of hands:**
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

(Contd. on page 4)

(Contd. of page 3)

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.

· **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 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**	
· **Appearance:**	
· **Form:**	Pasty
· **Colour:**	Red
· **Smell:**	Aromatic
· **Odour threshold:**	Not determined.
· **pH-value:**	Not determined.
· **Change in condition**	
· **Melting point/freezing point:**	Not determined
· **Initial boiling point and boiling range:**	≥300 °C
· **Flash point:**	21.1 °C
· **Inflammability (solid, gaseous)**	Not applicable.
· **Ignition temperature:**	234 °C
· **Decomposition temperature:**	Not determined.
· **Self-inflammability:**	Product is not selfigniting.
· **Explosive properties:**	Product is not explosive. However, formation of explosive air/vapour mixtures is possible.
· **Critical values for explosion:**	
· **Lower:**	1.3 Vol %
· **Upper:**	23 Vol %
· **Steam pressure:**	Not determined.
· **Density at 20 °C**	1.15 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.

(Contd. on page 5)

(Contd. of page 4)

· **kinematic:**	Not determined.
· **Solvent content:**	
· **Solids content:**	60.4 %
· **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**
· **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:** -

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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 that are relevant for classification:**		
Reaction product of tetraethoxysilane, alkylated polysilicate, dioctyltin oxide and benzoic acid		
Oral	LD50	>2000 mg/kg (nd)
112945-52-5 Amorphous silica		
Oral	LD50	>5000 mg/kg (rat) (OECD 401)
Dermal	LD50	>5000 mg/kg (rabbit)

· **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**
May cause an allergic skin reaction.
· **Additional toxicological information:**
· **Sensitisation** Guinea-Pig Maximisation Test (OECD 406): positive
· **CMR effects (carcinogenity, 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.

(Contd. on page 6)

(Contd. of page 5)

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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	>10000 mg/l (fish) (OECD 203)
EC50 / 24h	>1000 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.
· **Additional ecological information:**
· **General notes:** Avoid transfer into the environment.
· **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**
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**	
· **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)

(Contd. on page 7)

(Contd. of page 6)

· **14.3 Transport hazard class(es)**

· **ADR**

· **Class** 3 (F1) Flammable liquids.
· **Label** 3

· **IMDG, IATA**

· **Class** 3 Flammable liquids.
· **Label** 3

· **14.4 Packing group**
· **ADR, IMDG, IATA** II

· **14.5 Environmental hazards:**
· **Marine pollutant:** No

· **14.6 Special precautions for user** Warning: Flammable liquids.
· **Kemler Number:** 33
· **EMS Number:** F-E,S-E
· **Stowage Category** B

· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code** Not applicable.

· **Transport/Additional information:** -

· **ADR**
· **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
· **Transport category** 2
· **Tunnel restriction code** D/E

· **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

(Contd. on page 8)

Trade name: **Activator Universal Plus Paste**

(Contd. of page 7)

· **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:**
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.**