



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

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. 3 H226 Flammable liquid and vapour.

Acute Tox. 4 H332 Harmful if inhaled.

Eye Irrit. 2 H319 Causes serious eye irritation.

STOT SE 3 H335 May cause respiratory irritation.

STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.

· **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 GHS08

· **Signal word** Warning

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

tetraethyl orthosilicate

dioctyltin oxide

tetramethyl orthosilicate

· **Hazard statements**

H226 Flammable liquid and vapour.

H332 Harmful if inhaled.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H373 May cause damage to organs through prolonged or repeated exposure.

· **Precautionary statements**

P210

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

P241

Use explosion-proof electrical/ventilating/lighting/equipment.

(Contd. on page 2)

GB



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Activator Universal Plus paste

(Contd. of page 1)

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

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

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

P405 Store locked up.

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: -

Dangerous components:

CAS: 78-10-4 EINECS: 201-083-8 Reg.nr.: 01-2119496195-28-0003	tetraethyl orthosilicate Flam. Liq. 3, H226; Acute Tox. 4, H332; Eye Irrit. 2, H319; STOT SE 3, H335	10-25%
CAS: 870-08-6 EINECS: 212-791-1	dioctyltin oxide STOT RE 2, H373; Aquatic Chronic 4, H413	10-25%
CAS: 681-84-5 EINECS: 211-656-4	tetramethyl orthosilicate Flam. Liq. 2, H225; Acute Tox. 1, H330; Eye Dam. 1, H318; Acute Tox. 4, H302	< 1%

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

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· **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. If symptoms persist, 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

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Activator Universal Plus paste

(Contd. of page 2)

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
 - **Suitable extinguishing agents**
CO₂, extinguishing powder or water jet. Fight larger fire with alcohol-resistant foam.
 - **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:** Put on breathing apparatus.
 - **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.
- **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 13 for information on disposal.
See Section 8 for information on personal protection equipment.
-

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Keep containers tightly sealed.
Ensure good ventilation/exhaustion at the workplace.
Please observe the additional instructions in the product's instructions for use.
 - **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
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.

(Contd. on page 4)

GB



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Activator Universal Plus paste

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

(Contd. of page 3)

SECTION 8: Exposure controls/personal protection

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

· **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.

· **DNELs**

78-10-4 tetraethyl orthosilicate

Dermal	worker industr., acute, syst.	12.1 mg/Kg/d (human)
	worker industr., l.te., syst.	12.1 mg/Kg/d (human)
	ge.pop., acu., syst.	8.4 mg/Kg/d (human)
	ge.pop., l.te, syst.	8.4 mg/Kg/d (human)
Inhalative	worker industr., acute, syst.	85 mg/m3 (human)
	worker industr., l.te., syst.	85 mg/m3 (human)
	ge.pop., l.te, syst.	25 mg/m3 (human)

· **PNECs**

78-10-4 tetraethyl orthosilicate

freshwater	0.192 mg/l (aqua)
marine water	0.0192 mg/l (aqua)
interm. wat. release	10 mg/l (aqua)
sedim., dw, fre.wat.	0.18 mg/Kg (sediment)
soil,dw	0.05 mg/Kg (soil)

· **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**

Avoid contact with the eyes.

Keep away from foodstuffs, beverages and food.

Instantly remove any soiled and impregnated garments.

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

Do not inhale gases / fumes / aerosols.

Avoid contact with the eyes and skin.

· **Breathing equipment:** Not required.

· **Protection of hands:**

Impervious gloves

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.

(Contd. on page 5)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Activator Universal Plus paste

(Contd. of page 4)

- **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 protection:** Safety glasses
- **Body protection:** Protective work 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/Melting range:** Not determined
- **Boiling point/Boiling range:** 110 °C

· **Flash point:** 37 °C

· **Inflammability (solid, gaseous)** Not applicable.

· **Ignition temperature:**

- **Decomposition temperature:** Not determined.

· **Self-inflammability:** Product is not selfigniting.

· **Danger of explosion:** Product is not explosive. However, formation of explosive air/vapour mixtures is possible.

· **Critical values for explosion:**

- **Lower:** 1.3 Vol %
- **Upper:** 23.0 Vol %

· **Steam pressure at 20 °C:** 1.7 hPa

· **Density** Not determined

- **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.

(Contd. on page 6)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Activator Universal Plus paste

(Contd. of page 5)

- **Viscosity:**
 - **dynamic at 20 °C:** 100000 mPas
 - **kinematic:** Not determined.
- **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:** -

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
 - **Acute toxicity**
Harmful if inhaled.

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

112945-52-5 Kieselsäuren, amorphe

Oral LD50 > 10000 mg/kg (rat)

Dermal LD50 > 5000 mg/kg (rabbit)

78-10-4 tetraethyl orthosilicate

Oral LD50 6270 mg/kg (rat)

Dermal LD50 5878 mg/kg (can)

870-08-6 dioctyltin oxide

Oral LD50 > 4000 mg/kg (rat)

681-84-5 tetramethyl orthosilicate

Oral LD50 700 mg/kg (rat)

- **Primary irritant effect:**
 - **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
 - **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Sensitisation** Guinea-Pig Maximisation Test (OECD 406): positive
- **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.

(Contd. on page 7)

GB



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Activator Universal Plus paste

(Contd. of page 6)

- **STOT-repeated exposure**
May cause damage to organs through prolonged or repeated exposure.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

112945-52-5 Kieselsäuren, amorphe

LC50/96h >10000 mg/l (fish)

78-10-4 tetraethyl orthosilicate

EC50/48h >844 mg/l (daphnia)

870-08-6 dioctyltin oxide

EC50/48h 6.9 mg/l (daphnia)

LC50/96h 13 mg/l (fish)

- **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**

Small quantities can be polymerized with the matching system component(s) and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities.

· **European waste catalogue**

18 01 06 chemicals consisting of or containing dangerous substances

· **Uncleaned packagings:**

- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· **14.1 UN-Number**

· **ADR, IMDG, IATA**

UN1993

(Contd. on page 8)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Activator Universal Plus paste

(Contd. of page 7)

· 14.2 UN proper shipping name

· ADR

1993 FLAMMABLE LIQUID, N.O.S., special provision 640H (TETRAETHYL SILICATE, METHYL ORTHOSILICATE)
FLAMMABLE LIQUID, N.O.S. (TETRAETHYL SILICATE, METHYL ORTHOSILICATE)

· IMDG, IATA

· 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

III

· 14.5 Environmental hazards:

· Marine pollutant:

No

· 14.6 Special precautions for user

· Kemler Number:

30

· EMS Number:

F-E, S-E

Warning: Flammable liquids.

· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable.

· Transport/Additional information:

-

· ADR

· Limited quantities (LQ)

5L

· Excepted quantities (EQ)

Code: E1

Maximum net quantity per inner packaging:
30 ml

Maximum net quantity per outer packaging:
1000 ml

· Transport category

3

· Tunnel restriction code

D/E

(Contd. on page 9)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Activator Universal Plus paste

(Contd. of page 8)

· **UN "Model Regulation":**

UN1993, FLAMMABLE LIQUID, N.O.S., 3, III

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
 - **Directive 2012/18/EU**
 - **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
 - **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3, 20
- **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.
- H226 Flammable liquid and vapour.
- H302 Harmful if swallowed.
- H318 Causes serious eye damage.
- H319 Causes serious eye irritation.
- H330 Fatal if inhaled.
- H332 Harmful if inhaled.
- H335 May cause respiratory irritation.
- H373 May cause damage to organs through prolonged or repeated exposure.
- H413 May cause long lasting harmful effects to aquatic life.

· **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)
- 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
- Flam. Liq. 2: Flammable liquids – Category 2
- Flam. Liq. 3: Flammable liquids – Category 3
- Acute Tox. 1: Acute toxicity – Category 1
- Acute Tox. 4: Acute toxicity – Category 4
- Eye Dam. 1: Serious eye damage/eye irritation – Category 1
- Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
- STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
- STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
- Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

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