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

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#### SECTION 1: Identification of the substance/mixture and of the company, undertaking · 1.1 Product identifier - Trade name: Activator Universal Plus Liquid · 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 H225 Highly flammable liquid and vapour. Flam. Liq. 2 Acute Tox. 4 H332 Harmful if inhaled. Eve Irrit. 2 H319 Causes serious eye irritation. STOT SE 3 H335 May cause respiratory irritation. H373 May cause damage to organs through prolonged or repeated exposure. STOT RE 2 Aquatic Chronic 4 H413 May cause long lasting harmful effects to aquatic life. · 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 Danger · Hazard-determining components of labelling: tetraethyl orthosilicate dioctyltin oxide tetramethyl orthosilicate Hazard statements H225 Highly 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. H413 May cause long lasting harmful effects to aquatic life. (Contd. on page 2) GB



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Precautionary statements

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- Do not breathe dust/fume/gas/mist/vapours/spray. P260 P280 Wear protective gloves/protective clothing/eye protection/face protection. Avoid release to the environment. P273 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P313 Get medical advice/attention. P402 Store in a dry place. · 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: -

<ul> <li>Dangerous components:</li> </ul>		
CAS: 78-10-4	tetraethyl orthosilicate	25-50%
EINECS: 201-083-8 Reg.nr.: 01-2119496195-28-0003	Flam. Liq. 3, H226; Acute Tox. 4, H332; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 870-08-6	dioctyltin oxide	25-50%
EINECS: 212-791-1	STOT RE 2, H373; Aquatic Chronic 4, H413	
CAS: 681-84-5	tetramethyl orthosilicate	< 1%
EINECS: 211-656-4	Flam. Liq. 2, H225; Acute Tox. 1, H330; Eye Dam. 1, H318; Acute Tox. 4, H302	
Additional information For the wording of the listed beyond phrases refer to section 16		

• 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

Instantly wash with water and soap and rinse thoroughly. 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. Call a doctor immediately. In case of persistent symptoms consult doctor.

· 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

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• **4.3 Indication of any immediate medical attention and special treatment needed** No further relevant information available. (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

 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:
 Wear self-contained breathing apparatus.
 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: Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues). 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 Keep containers tightly sealed. Ensure good ventilation/exhaustion at the workplace. Prevent formation of aerosols. 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.

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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.

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

#### **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 in	dustr., 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 in	dustr., acute, syst.	85 mg/m3 (human)
	worker in	dustr., l.te., syst.	85 mg/m3 (human)
	ge.pop., l	.te, syst.	25 mg/m3 (human)
·	· PNECs		
78-10-4 tetraethyl orthosilicate			
freshwate	r	0.192 mg/l (aqua)	
marine water 0.0192 mg/l (aqua		0.0192 mg/l (aqua	
interm. wat. release 10 mg/l (aqua)		10 mg/l (aqua)	
sedim., dv	sedim., dw, fre.wat. 0.18 mg/Kg (sediment)		nent)

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.
     Avoid contact with the eyes and skin.
     Breathing equipment: Not required.
  - · Protection of hands:
  - Impervious gloves

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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 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: Safety glasses • Body protection: Protective work clothing.
- SECTION 9: Physical and chemical properties

General Information     Appearance:	
Form:	Fluid
· Colour:	Red
· Smell:	Aromatic
· Odour threshold:	Not determined.
· pH-value:	Not determined.
<ul> <li>Change in condition</li> <li>Melting point/Melting range:</li> <li>Boiling point/Boiling range:</li> </ul>	Not determined 110 °C
· Flash point:	21.1 °C
· Inflammability (solid, gaseous)	Not applicable.
· Ignition temperature:	345 ℃
· 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.
<ul> <li>Critical values for explosion:</li> <li>Lower:</li> <li>Upper:</li> </ul>	1.3 Vol % 23.0 Vol %
<ul> <li>Steam pressure at 50 °C:</li> </ul>	147 hPa (EG A4)
• Density at 20 °C • Relative density	1.058 g/cm <sup>3</sup> (DIN 51757) Not determined.

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<ul> <li>Vapour density</li> <li>Evaporation rate</li> </ul>	Not determined. Not determined.		
• Solubility in / Miscibility with • Water:	Not miscible or difficult to mix		
· Partition coefficient (n-octanol/	· Partition coefficient (n-octanol/water): Not determined.		
<ul> <li>Viscosity:</li> <li>dynamic:</li> <li>kinematic:</li> <li>9.2 Other information</li> </ul>	Not determined. Not determined. 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: -

SECT	ION 1	1: Toxicological information	
· Acu	te toxi	<b>ion on toxicological effects city</b> nhaled.	
· L	D/LC5	0 values that are relevant for classification:	
78-10-4	tetrae	thyl orthosilicate	
Oral	LD50	6270 mg/kg (rat)	
Dermal	LD50	5878 mg/kg (can)	
870-08-	6 dioc	tyltin oxide	
Oral	LD50	>4000 mg/kg (rat)	
681-84-	5 tetra	methyl orthosilicate	
Oral	Oral LD50 700 mg/kg (rat)		
· F	• Skin • Serio Caus Respira	v irritant effect: corrosion/irritation Based on available data, the classification criteria are not met. ous eye damage/irritation ses serious eye irritation. ntory or skin sensitisation Based on available data, the classification criteria are not met. fects (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.

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• **STOT-single exposure** May cause respiratory irritation.

· 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:				
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)				
<ul> <li>12.2 Persistence and degradability No further relevant information available.</li> <li>12.3 Bioaccumulative potential No further relevant information available.</li> <li>12.4 Mobility in soil No further relevant information available.</li> <li>Additional ecological information:         <ul> <li>General notes:</li> <li>Avoid transfer into the environment.</li> <li>Do not allow product to reach ground water, water bodies or sewage system.</li> <li>Danger to drinking water if even small quantities leak into soil.</li> </ul> </li> <li>12.5 Results of PBT and vPvB assessment         <ul> <li>VPB: Not applicable.</li> <li>VPVB: Not applicable.</li> </ul> </li> <li>12.6 Other adverse effects No further relevant information available.</li> </ul>				
SECTION 13: Disposal considerations				
<ul> <li>• 13.1 Waste treatment methods         <ul> <li>• Recommendation</li> <li>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.</li> </ul> </li> </ul>				

#### · Uncleaned packagings:

· Recommendation: Disposal must be made according to official regulations.

## **SECTION 14: Transport information**

· 14.1 UN-Number · ADR, IMDG, IATA

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· 14.2 UN proper shipping name	(Contd. of page
· 14.2 ON proper shipping hame · ADR	1993 FLAMMABLE LIQUID, N.O.S., spec provision 640D (TETRAETHYL SILICAT METHYL ORTHOSILICATE)
· IMDG	FLAMMABLE LIQUID, N.O.S. (TETRAETH' SILICATE, METHYL ORTHOSILICATE)
	Flammable liquid, n.o.s. (Tetraethyl silicat Methyl orthosilicate)
<ul> <li>14.3 Transport hazard class(es)</li> </ul>	
· ADR	
· Class · Label	3 (F1) Flammable liquids. 3
· IMDG, IATA	
· Class · Label	3 Flammable liquids. 3
· 14.4 Packing group · ADR, IMDG, IATA	11
<ul> <li>14.5 Environmental hazards:</li> <li>Marine pollutant:</li> </ul>	No
· 14.6 Special precautions for user	Warning: Flammable liquids.
· Kemler Number: · EMS Number:	30 F-E,S-E
· Stowage Category	A /
<ul> <li>14.7 Transport in bulk according to Anne.</li> <li>Marpol and the IBC Code</li> </ul>	x II of Not applicable.
· Transport/Additional information:	-
ADR	
<ul> <li>Limited quantities (LQ)</li> <li>Excepted quantities (EQ)</li> </ul>	5 L Code: E1
	Maximum net quantity per inner packagir 30 ml
	Maximum net quantity per outer packagir 1000 ml
· Transport category	3
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· Tunnel restriction code	D/E
<ul> <li>IMDG         <ul> <li>Limited quantities (LQ)</li> <li>Excepted quantities (EQ)</li> </ul> </li> </ul>	5 L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· UN "Model Regulation":	UN 1993 FLAMMABLE LIQUID, N.O.S., SPECIAL PROVISION 640D (TETRAETHYL SILICATE, METHYL ORTHOSILICATE), 3, II

## SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

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 eve 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 INDO: International Nanthine 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

- 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

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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.**