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

Printing date 28.09.2017 Version number 3 Revision: 28.09.2017

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

- · 1.1 Product identifier
 - . Trade name: Universal Adhesive
- · 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 Tray adhesive for use with silicone impression materials
- · 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. Lig. 2 H225 Highly flammable liquid and vapour.

Skin Irrit. 2 H315 Causes skin irritation.

Eye Dam. 1 H318 Causes serious eye damage.

- · 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 GHS05

- · Signal word Danger
- · Hazard-determining components of labelling:

titanium tetrabutanolate

· Hazard statements

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H318 Causes serious eve damage.

· Precautionary statements

P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

P241 Use explosion-proof electrical/ventilating/lighting/equipment.

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.

P310 Immediately call a POISON CENTER/doctor.

P321 Specific treatment (see on this label).

· 2.3 Other hazards -

· Results of PBT and vPvB assessment

· PBT: Not applicable.

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· vPvB: Not applicable.

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SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
 - Description: -

· Dangerous components:		
CAS: 141-78-6	ethyl acetate	10-25%
EINECS: 205-500-4	Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	
CAS: 1330-20-7	xylene, mixed isomers, pure	5-10%
EINECS: 215-535-7 Reg.nr.: 2119488216-32-xxxx	Flam. Liq. 3, H226; Acute Tox. 4, H312; Acute Tox. 4, H332; Skin Irrit. 2, H315	
CAS: 5593-70-4	titanium tetrabutanolate	0-5%
EINECS: 227-006-8	Flam. Liq. 3, H226; Eye Dam. 1, H318; Skin Irrit. 2, H315	
CAS: 100-41-4	ethylbenzene	0-5%
EINECS: 202-849-4	Flam. Liq. 2, H225; STOT RE 2, H373; Asp. Tox. 1, H304; Acute Tox. 4, H332	
CAS: 556-67-2	octamethylcyclotetrasiloxane	< 1%
EINECS: 209-136-7	Flam. Liq. 3, H226; Repr. 2, H361f; Aquatic Chronic 4, H413	

[·] 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

Instantly rinse with water.

If skin irritation continues, consult a doctor.

· After eve 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

No further relevant information available.

· 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

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.

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

- 5.3 Advice for firefighters
 - · Protective equipment: No special measures required.

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· Additional information -

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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: Prevent material from reaching sewage system, holes and cellars.

6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).

Do not flush with water or aqueous cleansing agents

· 6.4 Reference to other sections

No dangerous materials are released.

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.

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
 - - · Requirements to be met by storerooms and containers: Store in cool location.
 - Information about storage in one common storage facility: Not required.
 - · Further information about storage conditions:

Store in cool, dry conditions in well sealed containers.

· 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:

141-78-6 ethyl acetate

WEL Short-term value: 400 ppm

Long-term value: 200 ppm

1330-20-7 xylene, mixed isomers, pure

WEL Short-term value: 441 mg/m³, 100 ppm

Long-term value: 220 mg/m³, 50 ppm Sk; BMGV

100-41-4 ethylbenzene

WEL Short-term value: 552 mg/m³, 125 ppm

Long-term value: 441 mg/m³, 100 ppm

Sk

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· Ingredients with biological limit values:

1330-20-7 xylene, mixed isomers, pure

BMGV 650 mmol/mol creatinine

Medium: urine

Sampling time: post shift

Parameter: methyl hippuric acid

· 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 neccessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).

Protection of hands:

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: not absolutely neccessary
- · Body protection: Light weight protective clothing

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties General Information

· Appearance:

Form:

Fluid · Colour: Blue · Smell: Ester-like · Odour threshold: Not determined.

· pH-value: Not determined.

· Change in condition

· Melting point/Melting range: Not determined

77 °C · Boiling point/Boiling range:

· Flash point: 3 °C

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· Inflammability (solid, gaseous)	Not applicable.		
· Ignition temperature:	460 °C		
· 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: · Upper:	2.1 Vol % 11.5 Vol %		
· Steam pressure at 20 °C:	102 hPa		
 Density at 20 °C Relative density Vapour density Evaporation rate 	1.20169 g/cm³ Not determined. Not determined. Not determined.		
Solubility in / Miscibility with Water:	Not miscible or difficult to mix		
· Partition coefficient (n-octanol/wat	· Partition coefficient (n-octanol/water): Not determined.		
Viscosity: dynamic: kinematic: 9.2 Other information	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: -

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:			
141-78-6 eth	141-78-6 ethyl acetate		
Oral	LD50	5600 mg/kg (rat)	
Dermal	LD50	18000 mg/kg (rabbit)	
Sensitisation	Sensib.	nicht sensib. (guinea pig) (OECD-Prüfrichtlinie 406)	
1330-20-7 xylene, mixed isomers, pure			
Oral	LD50	8700 mg/kg (rat)	
Dermal	LD50	2000 mg/kg (rabbit)	

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Inhalative	LC50/4 h	6350 mg/l (rat)
100-41-4 ethylbenzene		
Oral	LD50	3500 mg/kg (rat)
Dermal	LD50	17800 mg/kg (rabbit)

- · Primary irritant effect:
 - · Skin corrosion/irritation

Causes skin irritation.

- Serious eye damage/irritation
 - Causes serious eye damage.
- · Respiratory or skin sensitisation

Based on available data, the classification criteria are not met.

- 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.

SECTION 12: Ecological information

- · 12.1 Toxicity
 - · Aquatic toxicity:

141-78-6 ethyl acetate

EC50/48h | 3300 mg/l (algae)

717 mg/l (daphnia) (DIN 38412)

LC50/96h 230 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.
- · 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.

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

SECTION 14: Transport information

- · 14.1 UN-Number
 - · **ADR, IMDG, IATA** UN1866

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(Contd. of page 6) · 14.2 UN proper shipping name · ADR 1866 RESIN SOLUTION, special provision 640D RESIN SOLUTION · IMDG, IATA · 14.3 Transport hazard class(es) · ADR 3 (F1) Flammable liquids. · Class · Label · IMDG, IATA · Class 3 Flammable liquids. · Label · 14.4 Packing group · ADR, IMĎĞ, 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 · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable. Transport/Additional information: · ADR · Limited quantities (LQ) · Excepted quantities (ÉQ) Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml · Transport category · Tunnel restriction code D/E · IMDG · Limited quantities (LQ) 5L Excepted quantities (ÉQ) Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml (Contd. on page 8)



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· UN "Model Regulation":

UN 1866 RESIN SOLUTION, SPECIAL

PROVISION 640D, 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
 - REGÚLATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- 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.

H304 May be fatal if swallowed and enters airways.

H312 Harmful in contact with skin.

H315 Causes skin irritation.

H318 Causes serious eye damage. H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H336 May cause drowsiness or dizziness.

H361f Suspected of damaging fertility.

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)
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. 4: Acute toxicity – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Eye Irrit. 2: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Repr. 2: Reproductive toxicity – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
Asp. Tox. 1: Aspiration hazard – Category 1

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4