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

Printing date 24.06.2024

Version number 4 (replaces version 3)

Revision: 24.06.2024

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 H225 Highly flammable liquid and vapour. Flam. Liq. 2 Skin Irrit. 2 H315 Causes skin irritation. Eve Dam. 1 H318 Causes serious eye damage. STOT SE 3 H336 May cause drowsiness or dizziness. Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects. · 2.2 Label elements Labelling according to Regulation (EC) No 1272/2008 The product is classified and labelled according to the GB CLP regulation. · Hazard pictograms GHS02 GHS05 GHS07 · Signal word Danger · Hazard-determining components of labelling: tetra-n-butoxytitanium ethyl acetate · Hazard statements H225 Highly flammable liquid and vapour. H315 Causes skin irritation. H318 Causes serious eye damage. H336 May cause drowsiness or dizziness. H412 Harmful to aquatic life with long lasting effects. Precautionary statements P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smokina. P273 Avoid release to the environment. P280 Wear protective gloves / eye protection. (Contd. on page 2)



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P280 Wear protective clothing. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P309+P311

IF exposed or if you feel unwell: Call a POISON ČENTER or doctor/physician.

· 2.3 Other hazards -

Results of PBT and vPvB assessment

· PBT:

556-67-2 octamethylcyclotetrasiloxane

· vPvB:

556-67-2 octamethylcyclotetrasiloxane

SECTION 3: Composition/information on ingredients

· 3.2 Mixtures

 Description: - 		
 Dangerous components: 		
CAS: 141-78-6 EINECS: 205-500-4 Index number: 607-022-00-5 Reg.nr.: 01-2119475103-46-xxxx	ethyl acetate Flam. Liq. 2, H225 Eye Irrit. 2, H319; STOT SE 3, H336 EUH066	<i>≥</i> 10- <i>≤</i> 25%
CAS: 1330-20-7 EINECS: 215-535-7 Index number: 601-022-00-9 Reg.nr.: 2119488216-32-xxxx	xylene, mixed isomers, pure Flam. Liq. 3, H226 Acute Tox. 4, H312; Acute Tox. 4, H332; Skin Irrit. 2, H315	<i>≥</i> 0-<10%
CAS: 5593-70-4 EINECS: 227-006-8	tetra-n-butoxytitanium Flam. Liq. 3, H226 Eye Dam. 1, H318 Skin Irrit. 2, H315; STOT SE 3, H335-H336	<i>≥</i> 3- <u>≤</u> 5%
CAS: 100-41-4 EINECS: 202-849-4 Index number: 601-023-00-4	ethylbenzene Flam. Liq. 2, H225 STOT RE 2, H373; Asp. Tox. 1, H304 Acute Tox. 4, H332	<i>≥</i> 0-≤5%
CAS: 556-67-2 EINECS: 209-136-7 Index number: 014-018-00-1 Reg.nr.: 01-2119529238-36-xxxx	octamethylcyclotetrasiloxane Flam. Liq. 3, H226 Repr. 2, H361f Aquatic Chronic 1, H410 (M=10) PBT; vPvB	<i>≥</i> 0.025-<0.25%
·SVHC		
556-67-2 octamethylcyclotetrasil	ovane	

556-67-2 octamethylcyclotetrasiloxane

• 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.

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(Contd. of page 2) • 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
- 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.
 - · 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: 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.

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- · 7.2 Conditions for safe storage, including any incompatibilities · Storage
 - 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

		tical values that require	monitoring at the workplace:	
	ethyl acetate			
WEL (Gre	eat Britain) Short-term value: 1468 r Long-term value: 734 mg			
IOELV (European Union) Short-term value: 146		Short-term value: 1468 r Long-term value: 734 mg		
1330-20-7	xylene, mixed	isomers, pure		
WEL (Gre	at Britain)	Short-term value: 441 m Long-term value: 220 m Sk; BMGV		
IOELV (Ei	ıropean Union)	Short-term value: 442 m Long-term value: 221 m Skin		
100-41-4	ethylbenzene			
WEL (Great Britain) Long-term value: 552 m Sk		g/m³, 125 ppm g/m³, 100 ppm		
IOELV (El	ıropean Union)	Short-term value: 884 m Long-term value: 442 m Skin		
· DN	ELs			
141-78-6	ethyl acetate			
Oral	general popula	tion, long term, systemic	4.5 mg/Kg (not defined)	
Dermal	worker industri	al, long term, systemic	63 mg/Kg/d (not defined)	
	general popula	tion, long term, systemic	37 mg/Kg/d (not defined)	
Inhalative	worker industri	al, acute, systemic	1,468 mg/m3 (not defined)	
	worker industrial, acute, local worker industrial, long term, systemic		1,468 mg/m3 (not defined)	
			734 mg/m3 (not defined)	
	worker industri	al, long term, local	734 mg/m3 (not defined)	
	general popula	tion, acute, systemic	734 mg/m3 (not defined)	
	general popula	tion, acute, local	734 mg/m3 (not defined)	
	general popula	tion, long term, systemic	367 mg/m3 (not defined)	



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	appared population long	torm local	(Contd. of page 4) 367 mg/m3 (not defined)	
556 67 2	general population, long			
	octamethylcyclotetrasil		2.7 mg/Kg (not defined)	
Oral Inholotivo		-	3.7 mg/Kg (not defined)	
Innalative	worker industrial, long te	-	73 mg/m3 (not defined)	
	worker industrial, long te		73 mg/m3 (not defined)	
		-	13 mg/m3 (not defined)	
	general population, long	term, local	13 mg/m3 (not defined)	
· PNE	ECs			
	ethyl acetate			
freshwater		0.24 mg/l (not	defined)	
marine wa	ter	0.024 mg/l (no	t defined)	
sewage tre	eatment plant	650 mg/l (not o	defined)	
sediment,	dry weight, freshwater	1.15 mg/Kg (n	ot defined)	
sediment,	dry weight, marine water	0.115 mg/Kg (not defined)	
soil, dry w	eight	0.148 mg/Kg ((not defined)	
556-67-2 (octamethylcyclotetrasil	oxane		
freshwater		0.0015 mg/l (n	0.0015 mg/l (not defined)	
marine wa	ter	0.00015 mg/l (not defined)		
sewage tre	eatment plant	10 mg/l (not de	10 mg/l (not defined)	
sediment,	dry weight, freshwater	3 mg/Kg (not d	defined)	
sediment,	dry weight, marine water	0.3 mg/Kg (no	t defined)	
· Ingi	redients with biological	limit values:		
1330-20-7	xylene, mixed isomers	, pure		
BMGV (Gr	reat Britain) 650 mmol/m			
	Medium: urii			
	Sampling tin	nethyl hippuric	acid	
· Ada			valid during the compilation were used as basis.	
			valid during the compliation were used as basis.	
	ure controls priate engineering cont	role No further	data: see section 7	
			sonal protective equipment	
	eral protective and hyg			
Avo	id contact with the eyes.			
	p away from foodstuffs, l			
Inst	antly remove any soiled a sh hands during breaks a	and impregnate	d garments. f the work	
	id contact with the eyes a		T THE WORK.	
	athing equipment:			
Not		nt local exhaus	t. If exposition to vapours is possible, use breathing	
Han	d protection ck protective gloves prio	r to each use fo	r their proper condition	
	ommended			
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· 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/face protection Tightly sealed safety glasses.

· Body protection: Light weight protective clothing

SECTION 9: Physical and chemical properties

General Information	F IL:
· Physical state	Fluid
· Colour:	Blue Foton like
· Smell:	Ester-like
Odour threshold:	Not determined.
• Melting point/freezing point:	Not determined
Boiling point or initial boiling point and	77 %0
boiling range	77 °C
Flammability	Not applicable.
Lower and upper explosion limit	0 4 1/-10/
Lower:	2.1 Vol %
· Upper:	11.5 Vol %
· Flash point:	3 °C
Auto-ignition temperature:	460 °C
• Decomposition temperature:	Not determined.
SADT	Not data wain ad
· pH	Not determined.
Viscosity:	Not determined
Kinematic viscosity	Not determined.
Kinematic viscosity	Not determined.
dynamic:	Not determined.
Solubility Water:	Not miscible or difficult to mix
Partition coefficient n-octanol/water (log	
value)	Not determined.
· Steam pressure at 20 °C:	102 hPa
· Vapour pressure:	
· Density and/or relative density	
· Density at 20 °C	1.20169 g/cm³
· Relative density	Not determined.



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· Vapour density	Not determined.
9.2 Other information	No further relevant information available.
· Appearance:	
Form:	Fluid
 Important information on protection of heal 	lth
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:	0.0 %
Change in condition	
· Evaporation rate	Not determined.
classes · Explosives · Flammable gases · Aerosols	Void Void Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Highly flammable liquid and vapour.
· 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: -

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11.1 Infor	mation or toxicity B	n hazard classes as defined in Regulation (EC) No 1272/2008 ased on available data, the classification criteria are not met.	
		les that are relevant for classification:	
	ethyl acet		
	LD50	>20,000 mg/kg (rabbit)	
1330-20-7	' xylene, n	nixed isomers, pure	
Oral	LD50	8,700 mg/kg (rat)	
Dermal	LD50	2,000 mg/kg (rabbit)	
Inhalative	LC50/4 h	6,350 mg/l (rat)	
100-41-4	ethylbenz	ene	
Oral	LD50	3,500 mg/kg (rat)	
Dermal	LD50	17,800 mg/kg (rabbit)	
		ylcyclotetrasiloxane	
Oral	LD50	>4,800 mg/kg (rat) (OECD 401)	
Dermal	LD50	>2,375 mg/kg (rat) (OECD 402)	
		36 mg/l (rat) (OECD 403)	
Cause	orrosion/i s skin irrita	ntion.	
		nage/irritation	
		eye damage. Skin sensitisation Based on available data, the classification criteria are n	ot mot
· Germ	cell mutac	genicity Based on available data, the classification criteria are not met.	ol mel.
· Carcin	nogenicity	Based on available data, the classification criteria are not met.	
		exicity Based on available data, the classification criteria are not met.	
	single exp	oosure siness or dizziness.	
		exposure Based on available data, the classification criteria are not met.	
		rd Based on available data, the classification criteria are not met.	
11.2 Infor	mation or	n other hazards	
		pting properties	
	,	/lcyclotetrasiloxane	List II;
540-97-6		ethylcyclohexasiloxane	List II
		nylcyclopentasiloxane	List II

12.1 Toxicity		
· Aquatic toxicity:		
141-78-6 ethyl acetate		
LC50/96h 230 mg/l (fis	h)	
NOEC / 21d 2.4 mg/l (dap	ohnia) (OECD 211)	



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NOEC / 72h	>100 mg/l (algae) (OECD 201)	(Contd. of page
	lene, mixed isomers, pure	
LC50/96h	13.4 mg/l (fish)	
	165 mg/l (daphnia)	
	amethylcyclotetrasiloxane	
	>0.015 mg/L (daphnia) (EPA OTS 797.1330)	
	>0.015 mg/l (daphnia) (EPA OTS 797.1300)	
LC50/96h	>0.022 mg/l (fish) (EPA OTS 797.1400)	
NOEC / 91d	≥0.0044 mg/l (fish)	
NOEC / 21d	≥0.015 mg/l (daphnia) (EPA OTS 797.1330)	
NOEC / 96h	<0.022 mg/l (algae) (EPA OTS 797.1050)	
	≥0.022 mg/l (fish) (EPA OTS 797.1400)	
NOEC / 48h	≥0.015 mg/l (daphnia) (EPA OTS 797.1300)	
ErC50/ 96h	>0.022 mg/L (algae) (EPA OTS 797.1050)	
	ence and degradability	
141-78-6 eth		
•	on 69 % /20d (not defined)	
100-41-4 eth		
-	on 68 % (not defined)	
	amethylcyclotetrasiloxane	
	on 3.7 % /29d (not defined) (OECD 310)	
	imulative potential	
141-78-6 eth		
	tion factor (BCF) 30 (not defined)	
	amethylcyclotetrasiloxane	
	tion factor (BCF) 12,400 (not defined)	
12.4 Mobility 12.5 Results	r in soil No further relevant information available. of PBT and vPvB assessment	
· PBT:		
556-67-2 oct	amethylcyclotetrasiloxane	
· vPvB:		
	amethylcyclotetrasiloxane	
12.6 Endocri	ne disrupting properties	
	on on endocrine disrupting properties see section 11.	
	l ecological information:	
· Genera	al notes:	
	allow product to reach ground water, water bodies or sewage system.	
Dange	r to drinking water if even small quantities leak into soil.	

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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.

14.1 UN number or ID number ADR, IMDG, IATA	UN1866
14.2 UN proper shipping name ADR IMDG, IATA	1866 RESIN SOLUTION, special provision 640 RESIN SOLUTION
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	11
14.5 Environmental hazards: • Marine pollutant:	No
14.6 Special precautions for user Kemler Number: EMS Number:	Warning: Flammable liquids. 33 F-E,S-E



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· Stowage Category	В
14.7 Maritime transport in bulk according to instruments	IMO Not applicable.
 Transport/Additional information: 	-
· ADR	
Limited quantities (LQ)	5L
Excepted quantities (ÉQ)	Code: E2
	Maximum net quantity per inner
	packaging: 30 ml
	Maximum net quantity per oute
	packaging: 500 ml
 Transport category 	2
• Tunnel restriction code	D/E
·IMDG	
· Limited quantities (LQ)	5L
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inne
	packaging: 30 ml
	Maximum net quantity per oute
	packaging: 500 ml
· 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 LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (UK ANNEX XIV)

• Substances of very high concern (SVHC) according to UK REACH

556-67-2 octamethylcyclotetrasiloxane

· 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

Highly flammable liquid and vapour. H225

H226 Flammable liquid and vapour.

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H304

H312

H315

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May be fatal if swallowed and enters airways.

Harmful in contact with skin.

Causes serious eye damage.

Causes skin irritation.

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H319 Causes serious eye irritation. H332 Harmful if inhaled. H335 May cause respiratory irritation. H336 May cause drowsiness or dizziness. H361f Suspected of damaging fertility. May cause damage to organs through prolonged or repeated exposure. H373 Very toxic to aquatic life with long lasting effects. H410 EUH066 Repeated exposure may cause skin dryness or cracking. 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) DNEL: Derived No-Effect Level (UK REACH) PNEC: Predicted No-Effect Concentration (UK 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. 4: Acute toxicity – Category 4 Skin Irrit. 2: Skin corrosion/irritation – Category 2 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 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 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3 * Date compared to the province version electron * Data compared to the previous version altered.