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

Printing date 05.12.2024

Version number 1

Revision: 05.12.2024

1 milling date 66.12.2621		1 (01)010111 00:12:2021
SECTION 1: Identificat undertaking	ion of the substance/mixt	ure and of the company/
• 1.1 Product identifier		
Trade name: Signum ui	niversal bond I	
	the substance or mixture and uses	s advised against
 Application of the substance 	ce / the mixture Dental bonding mate	rial
• 1.3 Details of the supplier of th • Manufacturer/Supplier: Kulzer GmbH	-	Tal - 140 (0)800 4373533
Leipziger Straße 2, 63450 Ha		Tel.: +49 (0)800 4372522
• Informing department: E-Ma • 1.4 Emergency telephone num	ail: msds@kulzer-dental.com ber: Emergency CONTACT (24-Hou	r-Number): +49 (0)6132-84463
SECTION 2: Hazards ider	tification	
2.1 Classification of the substa Classification according to	ance or mixture Regulation (EC) No 1272/2008	
Flam. Liq. 2 H225 Highly flam	•	
Eye Irrit. 2 H319 Causes se		
-	-	
STOT SE 3 H336 May cause	; alowsiness of alzziness.	
2.2 Label elements Labelling according to Reg The product is classified and Hazard pictograms	ulation (EC) No 1272/2008 labelled according to the CLP regulati	ion.
GHS02 GHS07		
· Signal word Danger		
· Hazard-determining com	ponents of labelling:	
acetone		
· Hazard statements	usid and some sur	
H225 Highly flammable liq		
H319 Causes serious eye H336 May cause drowsine		
· Precautionary statement		
P210 Keep away fr No smoking.	om heat, hot surfaces, sparks, open	flames and other ignition sources.
	ng dust/fume/gas/mist/vapours/spray.	
	ve gloves / eye protection.	-
• Additional information:	n persists: Get medical advice/attentio	<i>) </i> .
	e explosives precursors. Making avai	lable, introduction, possession and
use according to Regulation (EU) 2019/1148, Article 9.	
· 2.3 Other hazards -	, -,	
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· Results of PBT and vPvB assessment

SECTION 3: Composition/information on ingredients

• **PBT:** Not applicable.

· vPvB: Not applicable.

 Dangerous components: 		
CAS: 67-64-1 EINECS: 200-662-2 Index number: 606-001-00-8 Reg.nr.: 01-2119471330-49-xxxx	acetone Flam. Liq. 2, H225 Eye Irrit. 2, H319; STOT SE 3, H336 EUH066	>90%
CAS: 85590-00-7 EC number: 874-929-2	10-(Phosphonooxy)decyl methacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	0-5%
CAS: 64-19-7 EINECS: 200-580-7 Index number: 607-002-00-6 Reg.nr.: 01-2119475328-30-XXXX	acetic acid Flam. Liq. 3, H226 Skin Corr. 1A, H314; Eye Dam. 1, H318 (Specific concentration limits: Skin Corr. 1A; H314: C ≥ 90 % Skin Corr. 1B; H314: 25 % ≤ C < 90 % Skin Irrit. 2; H315: 10 % ≤ C < 25 % Eye Irrit. 2; H319: 10 % ≤ C < 25 %	<u>≥</u> 1-<35

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 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.

- 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.

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SECTION 5: Firefighting measures

· 5.1 Extinguishing media

· Suitable extinguishing agents

- CO2, extinguishing powder or water jet. Fight larger fires with water jet or 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: Wear self-contained breathing apparatus. Wear full protective suit.
 Additional information Cool endangered containers with water spray jet.

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Avoid contact with eyes and skin.
- 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). Ensure adequate ventilation.

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.

- 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:** Dry place, storage temperature <25 ° C
- Information about storage in one common storage facility: Not required.
- Further information about storage conditions: Store container in a well ventilated position.

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

8.1 Contro	ol parameters				
		tical valu	es that require	monitoring at the workplace:	
67-64-1 a					
OEL (Irela	nd)	Long-terr IOELV	n value: 1210 n	ng/m³, 500 ppm	
	ıropean Union)	Long-terr	n value: 1210 n	ng/m³, 500 ppm	
64-19-7 ad					
OEL (Ireland) Short-term Long-term IOELV		m value: 50 mg n value: 25 mg/	/m³, 20 ppm ′m³, 10 ppm		
IOELV (Ei	ıropean Union)	Short-teri Long-terr	m value: 50 mg n value: 25 mg/	/m³, 20 ppm /m³, 10 ppm	
· DN	ELs				
67-64-1 a	cetone				
Oral	general popula	tion, long	term, systemic	62 mg/Kg (not defined)	
Dermal	worker industri	al, long te	rm, systemic	186 mg/Kg/d (not defined)	
	general popula	tion, long	term, systemic	62 mg/Kg/d (not defined)	
Inhalative	worker industri	al, long te	rm, systemic	1,210 mg/m3 (not defined)	
	worker industri	al, long te	rm, local	2,420 mg/m3 (not defined)	
general population, long term, systemic		200 mg/m3 (not defined)			
· PNI	ECs				
67-64-1 a	cetone				
freshwater	~		10.6 mg/l (not	defined)	
marine wa	ter		1.06 mg/l (rabl	,	
sewage treatment plant 19.5 mg/l (not		defined)			
sediment,	dry weight, fres	hwater	30.4 mg/Kg (n		
sediment, dry weight, marine water 3.04 mg/Kg (n		3.04 mg/Kg (n	ot defined)		
•	l, dry weight 0.112 mg/Kg (not defined)				
· Add	litional informa	ation: The	e lists that were	valid during the compilation were u	sed as basis.
Appro Indivio Ger Avo Kee Inst		measure and hyg he eyes. odstuffs, b by soiled a	s, such as per ienic measure everages and f nd impregnated	ood. I garments.	
	id contact with t				
					(Contd. on page

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· Breathing equipment:

Filter AX.

Not neccessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).

Hand protection

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

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/face protection Tightly sealed safety glasses.

Body protection:

Protective work clothing.

Light weight protective clothing

9.1 Information on basic physical and chem General Information	ical properties	
· Physical state	Fluid	
· Colour:	Colourless	
· Smell:	Acetone-like	
· Odour threshold:	Not determined.	
• Melting point/freezing point:	Not determined	
Boiling point or initial boiling point ar		
boiling range	55.8-56.6 °C (67-64-1 acetone)	
· Flammability	Not applicable.	
[·] Lower and upper explosion limit		
· Lower:	2.6 Vol %	
Upper:	13 Vol %	
Flash point:	-3 °C	
 Decomposition temperature: 	Not determined.	
· SADT		
· pH at 20 °C	5-6	



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· Viscosity:	
· Kinematic viscosity	Not determined.
· Kinematic viscosity	
· 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:	247 hPa
· Vapour pressure:	
Density and/or relative density	
· Density at 20 °C	0.8 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· ·	
	lo further relevant information available.
Appearance:	
· Form:	Fluid
Important information on protection of healt	n
and environment, and on safety.	
Self-inflammability:	Product is not selfigniting.
• Explosive properties:	Product is not explosive. However, formation
	explosive air/vapour mixtures is possible.
Change in condition	
· Evaporation rate	Not determined.
Information with regard to physical hazard	d
classes	
· Explosives	Void
· Flammable gases	Void
Aerosols	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 Void

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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 hazard classes as defined in Regulation (EC) No 1272/2008 • Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50 values that are relevant for classification:

		es that are relevant for classification.
67-64-1 acet	tone	
Oral LL	D50	5,800 mg/kg (rat)
Dermal LL	D50	>15,800 mg/kg (rabbit)
Inhalative LC	C50/4 h	76 mg/l (rat)
64-19-7 acet	tic acid	
Oral LL	D50	3,310 mg/kg (rat)
Inhalative LC	C50/4 h	11.4 mg/l (rat) (OECD 403)
Causes s Respirato Germ cel Carcinog Reproduc STOT-sin May caus STOT-rep Aspiratio Subacute At long o solvent.	serious e ory or si ll mutag genicity totive to ngle exp se drows peated e on hazar e to chro or repeat ation on	nage/irritation ye irritation. kin sensitisation Based on available data, the classification criteria are not met. nenicity Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. xicity Based on available data, the classification criteria are not met. xicity Based on available data, the classification criteria are not met. sosure iness or dizziness. Exposure Based on available data, the classification criteria are not met. d Based on available data, the classification criteria are not met. d Based on available data, the classification criteria are not met. d Based on available data, the classification criteria are not met. d Based on available data, the classification criteria are not met. d Based on available data, the classification criteria are not met. d Based on available data, the classification criteria are not met. d Based on available data, the classification criteria are not met. d Based on available data, the classification criteria are not met. d Based on available data, the classification criteria are not met. d Based on available data, the classification criteria are not met. d Based on available data, the classification criteria are not met. d Based on available data, the classification criteria are not met. d Based on available data, the classification criteria are not met. d Based on available data, the classification criteria are not met. d Based on available data, the classification criteria are not met. d Based on available data, the classification criteria are not met. d Based on available data, the classification criteria are not met. d Based on available data, the classification criteria are not met. d Based on available data, the classification criteria are not met. d Based on available data, the classification criteria are not met. d Based on available data, the classification criteria are not met.

· Endocrine disrupting properties

128-37-0 2,6-di-tert-butyl-p-cresol

List II

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12.1 Toxicity	
· Aquatic t	
67-64-1 acet	
EC50/48h	8,800 mg/l (daphnia)
LC50/96h	6,210 mg/l (fish) (OECD 203)
64-19-7 acet	ic acid
EC50/48h	>300.82 mg/l (daphnia) (OECD 202)
LC50/96h	>1,000 mg/l (fish) (OECD 203)
ErC50 / 72 h	>1,000 mg/l (algae)
NOEC / 72h	1,000 mg/l (algae)
NOEC / 96h	1,000 mg/l (fish) (OECD 203)
12.2 Persist	ence and degradability
67-64-1 acet	
Biodegradati	on 90.9 % /28d (not defined) (OECD 301D)
64-19-7 acet	ic acid
12.3 Bioaccu 12.4 Mobility 12.5 Results PBT: Not	
12.3 Bioaccu 12.4 Mobility 12.5 Results PBT: Not vPvB: Not 12.6 Endocr For informati	inulative potential No further relevant information available. in soil No further relevant information available. of PBT and vPvB assessment applicable. t applicable. ine disrupting properties on on endocrine disrupting properties see section 11.
12.3 Bioaccu 12.4 Mobility 12.5 Results PBT: Not vPvB: Not 12.6 Endocr For informati 12.7 Other a	Imulative potential No further relevant information available. in soil No further relevant information available. of PBT and vPvB assessment applicable. t applicable. ine disrupting properties on on endocrine disrupting properties see section 11. dverse effects No further relevant information available.
12.3 Bioacce 12.4 Mobility 12.5 Results • PBT: Not • vPvB: Not 12.6 Endocr For informati 12.7 Other a SECTION	Imulative potential No further relevant information available. in soil No further relevant information available. of PBT and vPvB assessment applicable. tapplicable. in e disrupting properties on on endocrine disrupting properties see section 11. dverse effects No further relevant information available. 13: Disposal considerations
12.3 Bioacce 12.4 Mobility 12.5 Results • PBT: Not • vPvB: Not 12.6 Endocr For informatii 12.7 Other a SECTION 13.1 Waste to Recomm Must not system.	Imulative potential No further relevant information available. in soil No further relevant information available. of PBT and vPvB assessment applicable. tapplicable. on on endocrine disrupting properties see section 11. dverse effects No further relevant information available. 13: Disposal considerations reatment methods
12.3 Bioaccu 12.4 Mobility 12.5 Results • PBT: Not • vPvB: Not 12.6 Endocr For informatii 12.7 Other a SECTION 13.1 Waste to • Recomm Must not system. Disposal in • European	In soil No further relevant information available. of PBT and vPvB assessment applicable. t applicable. in e disrupting properties on on endocrine disrupting properties see section 11. dverse effects No further relevant information available. 13: Disposal considerations reatment methods endation be disposed of together with household garbage. Do not allow product to reach sew must be made according to official regulations. waste catalogue
12.3 Bioaccu 12.4 Mobility 12.5 Results • PBT: Not • vPvB: Not 12.6 Endocr For informatii 12.7 Other a SECTION 13.1 Waste to • Recomm Must not system. Disposal in • European	Invaluative potential No further relevant information available. In soil No further relevant information available. of PBT and vPvB assessment applicable. Ine disrupting properties on on endocrine disrupting properties see section 11. dverse effects No further relevant information available. 13: Disposal considerations reatment methods endation be disposed of together with household garbage. Do not allow product to reach sew must be made according to official regulations.

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14.1 UN number or ID number	11014000
· ADR, IMDG, IATA	UN1090
• 14.2 UN proper shipping name • ADR	1090 ACETONE solution
· ADR · IMDG, IATA	ACETONE solution
· 14.3 Transport hazard class(es)	
ADR	
· Class	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	Warning: Flammable liquids.
·Kemler Number: ·EMS Number:	33 F-E,S-D
• Stowage Category	F-E,S-D E
14.7 Maritime transport in bulk according	to IMO
instruments	Not applicable.
· Transport/Additional information:	-
• ADR • Limited quantities (LQ) • Excepted quantities (EQ)	1L Code:E2 Maximum net quantity per inr packaging:30ml Maximum net quantity per ou
Turners and a standard	packaging: 500 ml
 Transport category Tunnel restriction code 	2 D/E



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·IMDG	
 Limited quantities (LQ) 	
· Excepted quantities (ÉQ)	

· UN "Model Regulation":

packaging: 500 ml UN 1090 ACETONE SOLUTION. 3. II

packaging: 30 ml

Maximum net quantity per inner

Maximum net quantity per outer

1L Code: E2

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
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

 DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

REGULATION (EU) 2019/1148

 Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

no information available

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

67-64-1 acetone

· Regulation (EC) No 273/2004 on drug precursors

67-64-1 acetone

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

67-64-1 acetone

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.
- H314 Causes severe skin burns and eye damage.

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(Contd. of page 10) H315 Causes skin irritation. H318 Causes serious eye damage. Causes serious eye irritation. H319 H335 May cause respiratory irritation. May cause drowsiness or dizziness. H336 EUH066 Repeated exposure may cause skin dryness or cracking. Date of previous version: 12.03.2021 • Abbreviations and acronyms: 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 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 Elam Lin, 2: Elammable liquids – Category 2 VPVB: very Persistent and very Bioaccumulative Flam. Liq. 2: Flammable liquids – Category 2 Flam. Liq. 3: Flammable liquids – Category 3 Skin Corr. 1A: Skin corrosion/irritation – Category 1A 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 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 * Data compared to the provious version alfored * Data compared to the previous version altered.