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

Printing date 27.10.2022 Version number 1 Revision: 03.08.2022

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

- · 1.1 Product identifier
 - · Trade name: Signum universal bond I
- · 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 Dental bonding 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. 2 H225 Highly flammable liquid and vapour.

Eye Irrit. 2 H319 Causes serious eye irritation.

STOT SE 3 H336 May cause drowsiness or dizziness.

- · 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 GHS07

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

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition P210

sources. No smoking.

Avoid breathing dust/fume/gas/mist/vapours/spray. P261

P280 Wear protective gloves / eye protection.

P337+P313 If eye irritation persists: Get medical advice/attention.

- · 2.3 Other hazards
 - · Results of PBT and vPvB assessment
 - PBT: Not applicable.
 - vPvB: Not applicable.



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SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
 - · Description: -

· Dangerous components:		
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 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 %	0-5%

[·] 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 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.

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.

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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.

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

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

· Components with cri	· Components with critical values that require monitoring at the workplace:		
67-64-1 acetone			
WEL (Great Britain)	Short-term value: 3620 mg/m³, 1500 ppm Long-term value: 1210 mg/m³, 500 ppm		
IOELV (European Union)	Long-term value: 1210 mg/m³, 500 ppm		
64-19-7 acetic acid	64-19-7 acetic acid		
WEL (Great Britain)	Short-term value: 50 mg/m³, 20 ppm Long-term value: 25 mg/m³, 10 ppm		
IOELV (European Union)	Short-term value: 50 mg/m³, 20 ppm Long-term value: 25 mg/m³, 10 ppm		
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· DNI	ELs			
67-64-1 ad	cetone			
Oral	general population, long	term, systemic	62 mg/Kg (not defined)	
Dermal	worker industrial, long te	rm, systemic	186 mg/Kg/d (not defined)	
	general population, long	term, systemic	62 mg/Kg/d (not defined)	
Inhalative	worker industrial, long te	rm, systemic	1,210 mg/m3 (not defined)	
	worker industrial, long te	rm, local	2,420 mg/m3 (not defined)	
	general population, long	term, systemic	200 mg/m3 (not defined)	
·PNE	Cs			
67-64-1 ad	cetone			
freshwater	•	10.6 mg/l (not	defined)	
marine wa	ter	1.06 mg/l (rabl	bit)	
sewage tre	eatment plant	19.5 mg/l (not	defined)	
sediment,	dry weight, freshwater	30.4 mg/Kg (n	ot defined)	
sediment,	dry weight, marine water	3.04 mg/Kg (n	ot defined)	
soil, dry w	eight	0.112 mg/Kg (not defined)	

Additional information: The lists that were valid during the compilation were used as basis.

· 8.2 Exposure controls

- Appropriate engineering controls No further data; see item 7.
- Individual protection measures, such as 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:

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.

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· Body protection: Protective work clothing. Light weight protective clothing

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

General Information

Fluid Physical state · Colour: Colourless · Smell: Acetone-like Odour threshold: Not determined. Melting point/freezing point: Not determined

Boiling point or initial boiling point and

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 % <-18 °C Flash point: Not determined.

Decomposition temperature:

SADT

5-6 pH at 20 °C

Viscosity:

Kinematic viscosity Not determined. Not determined. dynamic:

· Solubility

Not miscible or difficult to mix Water:

· Partition coefficient n-octanol/water (log

Not determined.

Steam pressure at 20 °C: 247 hPa

Density and/or relative density

Density at 20 °C 0.8 g/cm³ Not determined. Relative density · Vapour density Not determined.

· 9.2 Other information No further relevant information available.

Appearance:

Fluid Form:

· Important information on protection of health 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.

· Change in condition · Evaporation rate Not determined.

· Information with regard to physical hazard

classes **Explosives** Void · Flammable gases Void

Void · Aerosols Oxidising gases Void · Gases under pressure Void

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· 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: -

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/	· LD/LC50 values that are relevant for classification:		
67-64-1 ad	67-64-1 acetone		
Oral	LD50	5,800 mg/kg (rat)	
Dermal	LD50	>15,800 mg/kg (rabbit)	
Inhalative	LC50/4 h	76 mg/l (rat)	
64-19-7 acetic acid			
Oral	LD50	3,310 mg/kg (rat)	
Inhalative	LC50/4 h	11.4 mg/l (rat) (OECD 403)	

- · 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.
- 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 drowsiness or dizziness.

- · 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.

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· Subacute to chronic toxicity:

At long or repeated contact with skin it may cause dermatitis due to the degreasing effect of the solvent.

· 11.2 Information on other hazards

· Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

•	•
67-64-1 acet	one
EC50/48h	8,800 mg/l (daphnia)
LC50/96h	6,210 mg/l (fish) (OECD 203)
64-19-7 acetic 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 Persistence and degradability

67-64-1 acetone

Biodegradation 90.9 % /28d (not defined) (OECD 301D)

64-19-7 acetic acid

Biodegradation 96 % /20d (not defined)

- · 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 Endocrine disrupting properties

For information on endocrine disrupting properties see section 11.

· 12.7 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.

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.

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14.1 UN number or ID number · ADR, IMDG, IATA	UN1090
14.2 UN proper shipping name · ADR · IMDG, IATA	1090 ACETONE solution ACETONE solution
•	ACE TONE Solution
14.3 Transport hazard class(es)	
· ADR	
· Class	3 (F1) Flammable liquids.
· Label	3`´
· IMDG, IATA	
· Class	3 Flammable liquids.
· Label	3
14.4 Packing group · ADR, IMDG, 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-D F
· Stowage Category	
14.7 Maritime transport in bulk accordin IMO instruments	i g to Not applicable.
· Transport/Additional information:	-
ADR	
· Limited quantities (LQ)	1L
Excepted quantities (ÉQ)	Code: E2
	Maximum net quantity per inner packagir
	30 ml Maximum net quantity per outer packagir
	500 ml
· Transport category	2
Tunnel restriction code	D/E
· IMDG	
· Limited quantities (LQ)	1L
Excepted quantities (ÉQ)	Code: E2
	Maximum net quantity per inner packagir
	30 ml Maximum net quantity per outer packagin
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500 ml

· UN "Model Regulation":

UN 1090 ACETONE SOLUTION, 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
- 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.

H226 Flammable liquid and vapour.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H336 May cause drowsiness or dizziness.

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

GHS: Globally Harmonised System of Classification and Labelling of Chemical 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

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 previous version altered.