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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**
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves / eye protection.
P337+P313 If eye irritation persists: Get medical advice/attention.
· **Additional information:**
Product contains: Reportable explosives precursors. Making available, 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**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**
· **Description:** -

· **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 %	≥1-<3%

· **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.

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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.

SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**

· **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	
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

· **DNELs**		
67-64-1 acetone		
Oral	general population, long term, systemic	62 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	186 mg/Kg/d (not defined)
	general population, long term, systemic	62 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	1,210 mg/m3 (not defined)
	worker industrial, long term, local	2,420 mg/m3 (not defined)
	general population, long term, systemic	200 mg/m3 (not defined)

· **PNECs**	
67-64-1 acetone	
freshwater	10.6 mg/l (not defined)
marine water	1.06 mg/l (rabbit)
sewage treatment plant	19.5 mg/l (not defined)
sediment, dry weight, freshwater	30.4 mg/Kg (not defined)
sediment, dry weight, marine water	3.04 mg/Kg (not defined)
soil, dry weight	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 section 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.

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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

*

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**
· **General Information**

· **Physical state**	Fluid
· **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 %
· **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/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.

· **9.2 Other information**	No further relevant information available.
· **Appearance:**	
· **Form:**	Fluid
· **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
· **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

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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:**		
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.
· **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**		
128-37-0	2,6-di-tert-butyl-p-cresol	List II

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SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**	
67-64-1 acetone	
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.

SECTION 14: Transport information

· **14.1 UN number or ID number**
· **ADR, IMDG, IATA** UN1090

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· **14.2 UN proper shipping name**
· **ADR** 1090 ACETONE solution
· **IMDG, IATA** ACETONE 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
· **Stowage Category** E

· **14.7 Maritime transport in bulk according to IMO instruments** Not applicable.

· **Transport/Additional information:** -

· **ADR**
· **Limited quantities (LQ)** 1L
· **Excepted quantities (EQ)** Code: E2
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 500 ml
· **Transport category** 2
· **Tunnel restriction code** D/E

· **IMDG**
· **Limited quantities (LQ)** 1L
· **Excepted quantities (EQ)** Code: E2
Maximum net quantity per inner packaging: 30 ml

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·	*Maximum net quantity per outer packaging: 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***
H225 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
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

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STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
· **** Data compared to the previous version altered.***