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

· **1.1 Product identifier**

· **Trade name:** **Signum ceramic 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** Auxiliary for manufacture of dental prothesis

· **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 CLP regulation.

· **Hazard pictograms**

GHS02 GHS07

· **Signal word** Danger

· **Hazard-determining components of labelling:**
propan-2-ol

· **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 mist/vapours/spray.
P280 Wear protective gloves / eye protection.

· **Additional information:**
Contains methyl methacrylate. May produce an allergic reaction.

· **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:**

CAS: 67-63-0 EINECS: 200-661-7	propan-2-ol Flam. Liq. 2, H225 Eye Irrit. 2, H319; STOT SE 3, H336	75-90%
CAS: 67-64-1 EINECS: 200-662-2 Reg.nr.: 01-2119471330-49-xxxx	acetone Flam. Liq. 2, H225 Eye Irrit. 2, H319; STOT SE 3, H336 EUH066	≥5-<10%
CAS: 80-62-6 EINECS: 201-297-1	methyl methacrylate Flam. Liq. 2, H225 Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	≥0.1-<1%

· **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. If symptoms persist, 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.
· **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.
Avoid contact with eyes and skin.

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· ***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.
· ***6.4 Reference to other sections***
No dangerous materials are released.
See Section 8 for information on personal protection equipment.
-

SECTION 7: Handling and storage

· ***7.1 Precautions for safe handling*** *Keep containers tightly sealed.*
· ***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:*** *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

· ***8.1 Control parameters***

· **Components with critical values that require monitoring at the workplace:**	
67-63-0 propan-2-ol	
OEL (Ireland)	Short-term value: 400 ppm Long-term value: 200 ppm Sk
67-64-1 acetone	
OEL (Ireland)	Long-term value: 1210 mg/m³, 500 ppm IOELV
IOELV (European Union)	Long-term value: 1210 mg/m³, 500 ppm
80-62-6 methyl methacrylate	
OEL (Ireland)	Short-term value: 100 ppm Long-term value: 50 ppm IOELV, Sens
IOELV (European Union)	Short-term value: 100 ppm Long-term value: 50 ppm

· **DNELs**		
67-63-0 propan-2-ol		
Oral	general population, long term, systemic	26 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	888 mg/Kg/d (not defined)
	general population, long term, systemic	319 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	500 mg/m3 (not defined)
	general population, long term, systemic	89 mg/m3 (not defined)

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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)
80-62-6 methyl methacrylate		
Oral	general population, long term, systemic	8.2 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	13.67 mg/Kg/d (not defined)
	general population, long term, systemic	8.2 mg/Kg/d (not defined)
Inhalative	worker industrial, acute, local	416 mg/m3 (not defined)
	worker industrial, long term, systemic	348.4 mg/m3 (not defined)
	worker industrial, long term, local	208 mg/m3 (not defined)
	general population, acute, local	208 mg/m3 (not defined)
	general population, long term, systemic	74.3 mg/m3 (not defined)

· **PNECs**

67-63-0 propan-2-ol	
freshwater	140.9 mg/l (not defined)
marine water	140.9 mg/l (not defined)
sewage treatment plant	2,251 mg/l (not defined)
sediment, dry weight, freshwater	552 mg/Kg (not defined)
sediment, dry weight, marine water	552 mg/Kg (not defined)
soil, dry weight	28 mg/Kg (not defined)
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)
80-62-6 methyl methacrylate	
freshwater	0.94 mg/l (not defined)
marine water	0.094 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)
sediment, dry weight, freshwater	10.2 mg/Kg (not defined)
sediment, dry weight, marine water	0.102 mg/Kg (not defined)
soil, dry weight	1.48 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.

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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).

· ***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:*** *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:***	*Alcohol-like*
· ***Odour threshold:***	*Not determined.*
· ***Melting point/freezing point:***	*Not determined*
· ***Boiling point or initial boiling point and boiling range***	*55 °C*
· ***Flammability***	*Not applicable.*
· ***Lower and upper explosion limit***	
· ***Lower:***	*2.0 Vol %*
· ***Upper:***	*12.0 Vol %*
· ***Flash point:***	*5 °C*
· ***Ignition temperature:***	*>400 °C*
· ***Decomposition temperature:***	*Not determined.*
· ***SADT***	
· ***pH***	*Mixture is non-soluble (in water).*
· ***Viscosity:***	
· ***Kinematic viscosity***	*Not determined.*
· ***dynamic:***	*Not determined.*

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· **Solubility**	
· **Water:**	Fully miscible
· **Partition coefficient n-octanol/water (log value)**	Not determined.
· **Steam pressure at 20 °C:**	48 hPa
· **Density and/or relative density**	
· **Density at 20 °C**	0.800 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.
· **Solvent content:**	
· **VOC EU**	769.7 g/l
· **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

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.

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· **10.6 Hazardous decomposition products:** None

*

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:		
67-63-0 propan-2-ol		
Oral	LD50	5,840 mg/kg (rat) (OECD 401)
Dermal	LD50	>12,800 mg/kg (rabbit) (OECD 402)
Inhalative	LC0	≥10,000 ppm /6h (rat) (OECD 403)
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)
80-62-6 methyl methacrylate		
Oral	LD50	~7,900 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (guinea pig) (OECD 402)
Inhalative	LC50/4 h	29.8 mg/l (rat)

· **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.

· **11.2 Information on other hazards**

· Endocrine disrupting properties
None of the ingredients is listed.

*

SECTION 12: Ecological information

· **12.1 Toxicity**

· Aquatic toxicity:	
67-63-0 propan-2-ol	
LC50/96h	9,640 mg/l (fish) (OECD 203)
LC50/24h	>10,000 mg/L (daphnia) (OECD 202)
67-64-1 acetone	
EC50/48h	8,800 mg/l (daphnia)
LC50/96h	6,210 mg/l (fish) (OECD 203)
80-62-6 methyl methacrylate	
EC50/21d	49 mg/L (daphnia) (OECD 211)
EC50/48h	69 mg/l (daphnia) (EPA OTS 797.1300)

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NOEC / 21d	37 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	>110 mg/l (algae) (OECD 201)
NOEC / 72h	110 mg/l (algae) (OECD 201)
NOEC / 48h	48 mg/l (daphnia) (EPA OTS 797.1300)
EbC50 / 72h	>110 mg/l (algae) (OECD 201)
NOEC/ 35d	9.4 mg/L (fish) (OECD 210)
LC50/ 35d	33.7 mg/L (fish) (OECD 210)

· **12.2 Persistence and degradability**

67-63-0 propan-2-ol	
Biodegradation	53 % /5d (not defined) (EU C.5)
67-64-1 acetone	
Biodegradation	90.9 % /28d (not defined) (OECD 301D)
80-62-6 methyl methacrylate	
Biodegradation	94 % /14d (not defined) (OECD 301C)

· **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**
· **Additional ecological information:**
· **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

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.

· **European waste catalogue**	
18 01 06*	chemicals consisting of or containing hazardous substances

· **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** UN1993

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· **14.2 UN proper shipping name**
· **ADR** 1993 FLAMMABLE LIQUID, N.O.S., special provision 640D (ISOPROPANOL (ISOPROPYL ALCOHOL), ACETONE)
· **IMDG, IATA** FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL), ACETONE)

· **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-E
· **Stowage Category** B

· **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

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· **Excepted quantities (EQ)**	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· **UN "Model Regulation":**	UN 1993 FLAMMABLE LIQUID, N.O.S., SPECIAL PROVISION 640D (ISOPROPANOL (ISOPROPYL ALCOHOL), ACETONE), 3, II

SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Directive 2012/18/EU**
· **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	3
7647-01-0	hydrogen chloride	3

· **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	3
7647-01-0	hydrogen chloride	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.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
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.

· **Date of previous version:** 03.08.2022

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· ***Version number of previous version:*** *3*
· ***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)
VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)
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
Flam. Liq. 2: Flammable liquids – Category 2
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
· **** Data compared to the previous version altered.***