

Page 1/9

Revision: 25.11.2022

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

Printing date 25.11.2022

Version number 5 (replaces version 3)

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

- · 1.1 Product identifier
 - · Trade name: Signum metal 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 Metal-Resin Bonding System
- · 1.3 Details of the supplier of the safety data sheet
 - Manufacturer/Supplier:

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

· 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 mist/vapours/spray.
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.

- GI



Page 2/9

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

Printing date 25.11.2022

Version number 5 (replaces version 3)

Trade name: Signum metal bond I

(Contd. of page 1)

Revision: 25.11.2022

SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
 - · Description: -

· Dangerous components:		
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	>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 %	≥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 rinse with water.

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. 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.

(Contd. on page 3)



Page 3/9

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

Printing date 25.11.2022 Version number 5 (replaces version 3) Revision: 25.11.2022

Trade name: Signum metal bond I

· Additional information -

(Contd. of page 2)

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.

Use breathing protection against the effects of fumes/dust/aerosol.

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 13 for information on disposal.

See Section 8 for information on personal protection equipment.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Keep containers tightly sealed.

Ensure good ventilation/exhaustion at the workplace.

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:		
67-64-1 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	
		(Contd. on pag



Page 4/9

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

Printing date 25.11.2022

Version number 5 (replaces version 3)

Revision: 25.11.2022

Trade name: Signum metal bond I

(Contd.	of	page	3)
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				(Conta. or page 3)
· DNI	DNELs			
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 term, systemic		1,210 mg/m3 (not defined)	
	worker industrial, long term, local general population, long term, systemic		2,420 mg/m3 (not defined)	
			200 mg/m3 (not defined)	
PNECs				
67-64-1 ad	cetone			
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 (n	ot defined)	
sediment,	dry weight, marine water	3.04 mg/Kg (n	ot 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 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.

(Contd. on page 5)



Page 5/9

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

Printing date 25.11.2022 Version number 5 (replaces version 3) Revision: 25.11.2022

Trade name: Signum metal bond I

(Contd. of page 4)

· 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 Not determined. Odour threshold: 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: 2.6 Vol % · Upper: 13.0 Vol %

-17 °C (67-64-1 acetone) Flash point: · Ignition temperature: 465 °C (67-64-1 acetoné)

Decomposition temperature: Not determined.

SADT

pH at 20 °C 5-6

Viscosity:

Kinematic viscosity Not determined. dynamic: Not determined.

Solubility Water:

Not miscible or difficult to mix

· Partition coefficient n-octanol/water (log

Not determined.

Steam pressure at 20 °C: 247 hPa

Density and/or relative density

· Density Not determined Relative density Not determined. · 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.
Product is not explosive. However, formation of · Explosive properties:

explosive air/vapour mixtures is possible.

· Change in condition

Not determined. Evaporation rate

· Information with regard to physical hazard

classes

Explosives Void Void Flammable gases Void · Aerosols · Oxidising gases Void

(Contd. on page 6)



Page 6/9

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

Printing date 25.11.2022 Version number 5 (replaces version 3) Revision: 25.11.2022

Trade name: Signum metal bond I

(Contd. of page 5)

	(Conta. or page 5)
· 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: -

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 ad	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 sérious 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.

(Contd. on page 7)



Page 7/9

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

Printing date 25.11.2022

Version number 5 (replaces version 3)

(Contd. of page 6)

Revision: 25.11.2022

Trade name: Signum metal bond I

· 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:

1		
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.

GB



Page 8/9

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

Printing date 25.11.2022

Version number 5 (replaces version 3)

Revision: 25.11.2022

Trade name: Signum metal bond I

(Contd. of page 7)

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
14.3 Transport hazard class(es)	
· ADR	
· Class	3 (F1) Flammable liquids. 3
Label	ა
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 · Kemler Number: · EMS Number: · Stowage Category	Warning: Flammable liquids. 33 F-E,S-D E
14.7 Maritime transport in bulk according IMO instruments	i to Not applicable.
· Transport/Additional information:	-
· ADR	
· Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packagin 30 ml Maximum net quantity per outer packagin
· Transport category	500 ml 2
Tunnel restriction code	D/E
· IMDG	
· Limited quantities (LQ)	1L
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packagin
	30 ml Maximum net quantity per outer packagin
	(Contd. on page



Page 9/9

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

Printing date 25.11.2022

Version number 5 (replaces version 3)

Revision: 25.11.2022

Trade name: Signum metal bond I

(Contd. of page 8)

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
 - 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.

H225 Highly flammable liquid and vapour.

H226 Flammable liquid and vapour.

Causes severe skin burns and eye damage. H314

H315 Causes skin irritation.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

May cause respiratory irritation. H335

May cause drowsiness or dizziness. H336

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

INDG: International Mantime 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

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.