



Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 17.02.2025

Version number 3

Revision: 17.02.2025

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

- **1.1 Product identifier**
 - Trade name: **Signum Insulating Pen 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:**

butanone
- **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.
P260	Do not breathe mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312	Call a POISON CENTER/doctor if you feel unwell.
P337+P313	If eye irritation persists: Get medical advice/attention.

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- **Additional information:**
EUH066 Repeated exposure may cause skin dryness or cracking.
- **2.3 Other hazards -**
- **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

· Determination of endocrine-disrupting properties	
78-93-3 butanone	List II

SECTION 3: Composition/information on ingredients

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

· Dangerous components:			
CAS: 78-93-3	butanone	Flam. Liq. 2, H225	≥50-≤90%
EINECS: 201-159-0		Eye Irrit. 2, H319; STOT SE 3, H336	
Index number: 606-002-00-3		EUH066	

- **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 fire with alcohol-resistant foam.
- **5.2 Special hazards arising from the substance or mixture**
Can form explosive gas-air mixtures.
Carbon monoxide (CO)
Formation of toxic gases is possible during heating or in case of fire.
- **5.3 Advice for firefighters**
 - **Protective equipment:** No special measures required.

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· **Additional information -**

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SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
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).
- **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.
Avoid contact with eyes and skin.
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:** 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.
Protect from heat and direct sunlight.
- **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:**

78-93-3 butanone

OEL (Ireland)	Short-term value: 900 mg/m ³ , 300 ppm Long-term value: 600 mg/m ³ , 200 ppm Sk, IOELV
IOELV (European Union)	Short-term value: 900 mg/m ³ , 300 ppm Long-term value: 600 mg/m ³ , 200 ppm

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· DNELs		
78-93-3 butanone		
Oral	general population, long term, systemic	31 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	1,161 mg/Kg/d (not defined)
	general population, long term, systemic	412 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	600 mg/m ³ (not defined)
	general population, long term, systemic	106 mg/m ³ (not defined)

· PNECs	
78-93-3 butanone	
freshwater	55.8 mg/l (not defined)
marine water	55.8 mg/l (not defined)
sewage treatment plant	709 mg/l (not defined)
sediment, dry weight, freshwater	284.74 mg/Kg (not defined)
sediment, dry weight, marine water	284.7 mg/Kg (not defined)
soil, dry weight	22.5 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.

· **Breathing equipment:**

Not necessary 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

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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 | Liquid |
| · Colour: | Colourless |
| · Smell: | Type specific |
| · Odour threshold: | Not determined. |
| · Melting point/freezing point: | Not determined |
| · Boiling point or initial boiling point and boiling range | 79 °C |
| · Flammability | Not applicable. |
| · Lower and upper explosion limit | |
| · Lower: | Not determined. |
| · Upper: | Not determined. |
| · Flash point: | -4 °C (78-93-3 butanone) |
| · Decomposition temperature: | Not determined. |
| · SADT | |
| · pH at 20 °C | 6-8 |
| · Viscosity: | |
| · Kinematic viscosity | Not determined. |
| · dynamic: | Not determined. |
| · Solubility | |
| · Water: | Not miscible or difficult to mix |
| · Partition coefficient n-octanol/water (log value) | Not determined. |
| · Steam pressure at 24 °C: | 83 mmHg |
| · Density and/or relative density | |
| · Density at 20 °C | 0.86 g/cm ³ |
| · 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.

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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** Heat, flames and sparks.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** Carbon dioxide
 - **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:

78-93-3 butanone

Oral	LD50	2,193 mg/kg (rat) (OECD 423)
Dermal	LD50	8,100 mg/kg (rabbit) (OECD 402)
Inhalative	LC50/4 h	40 mg/l (mouse)

- **Primary irritant effect:**
 - **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.

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- **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	
78-93-3 butanone	List II

SECTION 12: Ecological information

· **12.1 Toxicity**

· Aquatic toxicity:	
78-93-3 butanone	
EC50/48h	308 mg/l (daphnia) (OECD 202)
LC50/96h	2,993 mg/l (fish) (OECD 203)
ErC50 / 72 h	1,972 mg/l (algae) (OECD 201)
NOEC / 96h	1,170 mg/l (fish) (OECD 203)
NOEC / 48h	68 mg/l (daphnia) (OECD 202)
ErC10/72h	1,289 mg/L (algae) (OECD 201)

· **12.2 Persistence and degradability**

78-93-3 butanone	
Biodegradation	98 % /28d (not defined) (OECD 301D)

· **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.

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· **European waste catalogue**

18 01 06* | chemicals consisting of or containing hazardous substances

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

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

UN1193

· **14.2 UN proper shipping name**
· **ADR**

1193 ETHYL METHYL KETONE (METHYL ETHYL KETONE)
ETHYL METHYL KETONE (METHYL ETHYL KETONE)

· **IMDG, IATA**

· **14.3 Transport hazard class(es)**

· **ADR**



· **Class**
· **Label**

3 (F1) Flammable liquids.
3

· **IMDG, IATA**



· **Class**
· **Label**

3 Flammable liquids.
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**

B

· **14.7 Maritime transport in bulk according to IMO instruments**

Not applicable.

· **Transport/Additional information:**

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· 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 Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1193 ETHYL METHYL KETONE (METHYL ETHYL KETONE), 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

· **Regulation (EU) No 649/2012**

None of the ingredients are included.

· **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**

no information available

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

78-93-3 butanone

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

78-93-3 butanone

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· **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.
- H319 Causes serious eye irritation.
- H336 May cause drowsiness or dizziness.
- EUH066 Repeated exposure may cause skin dryness or cracking.

· **Date of previous version:** 30.06.2021

· **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 (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
- 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.**