



**Safety Data Sheet
according to WHS Regulations**

Date of issue: 17.02.2025

Version number 3

Revision: 17.02.2025

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

· **Other means of identification**

· Trade name: **Signum Insulating Pen I**

· **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

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**
Kulzer Australia Pty Ltd
Unit 20, 53 Lorraine St
PEAKHURST NSW 2210
Australia

Tel: +61 (02) 9153 0311

· **Informing department:** see above

· **Emergency telephone number:**
Poison Information Number: Australia 13 11 26 & New Zealand 0800 764 766

2 Hazard(s) Identification

· **Classification of the substance or mixture**

Flammable liquids – Category 2	H225	Highly flammable liquid and vapour.
Eye damage/irritation – Category 2A	H319	Causes serious eye irritation.
Specific target organ toxicity (single exposure) – Category 3	H335-H336	May cause respiratory irritation. May cause drowsiness or dizziness.

· **Label elements**

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS02 GHS07

· **Signal word** Danger

· **Hazard statements**

Highly flammable liquid and vapour.
Causes serious eye irritation.
May cause respiratory irritation. May cause drowsiness or dizziness.

· **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. No smoking.
Do not breathe mist/vapours/spray.
Wear protective gloves/protective clothing/eye protection/face protection.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Call a POISON CENTER/doctor if you feel unwell.
If eye irritation persists: Get medical advice/attention.

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

3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**

- **Description:** -

- **Dangerous components:**

78-93-3	butanone Flammable liquids – Category 2, H225 Eye damage/irritation – Category 2A, H319; Specific target organ toxicity (single exposure) – Category 3, H335-H336	≥50-≤90%
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- **Additional information** For the wording of the listed hazard phrases refer to section 16.

4 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.
- **Information for doctor**
 - **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
 - **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- **Suitable extinguishing agents**
CO₂, extinguishing powder or water jet. Fight larger fire with alcohol-resistant foam.
- **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.
- **Protective equipment:** No special measures required.
- **Additional information -**

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6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Prevent material from reaching sewage system, holes and cellars.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
- **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.

7 Handling and Storage

- **Handling**
 - **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.
- **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.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Appropriate engineering controls** No further data; see section 7.
- **Components with critical values that require monitoring at the workplace:**

78-93-3 butanone

WES (Australia)	Short-term value: 890 mg/m ³ , 300 ppm Long-term value: 445 mg/m ³ , 150 ppm
PEL (USA)	Long-term value: 590 mg/m ³ , 200 ppm
REL (USA)	Short-term value: 885 mg/m ³ , 300 ppm Long-term value: 590 mg/m ³ , 200 ppm
TLV (USA)	Short-term value: 885 mg/m ³ , 300 ppm Long-term value: 590 mg/m ³ , 200 ppm BEI

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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/m3 (not defined)
	general population, long term, systemic	106 mg/m3 (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)

· Ingredients with biological limit values:	
78-93-3 butanone	
BEI (USA)	2 mg/L Medium: urine Time: end of shift Parameter: MEK

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

· **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).

· **Protection of hands:**

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.

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- **Penetration time of glove material**
The exact break through 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 protection:** Tightly sealed safety glasses.
- **Body protection:** Light weight protective clothing

9 Physical and Chemical Properties

- **General Information**
- **Appearance:**
- **Form:** Fluid
- **Colour:** Colourless
- **Smell:** Type specific
- **Odour threshold:** Not determined.
- **pH-value at 20 °C:** 6-8
- **Change in condition**
- **Melting point/freezing point:** Not determined
- **Initial boiling point and boiling range:** 79 °C
- **Flash point:** -4 °C
- **Inflammability (solid, gaseous)** Not applicable.
- **Decomposition temperature:** Not determined.
- **Self-inflammability:** Product is not selfigniting.
- **Explosive properties:** Product is not explosive. However, formation of explosive air/vapour mixtures is possible.
- **Critical values for explosion:**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Steam pressure at 24 °C:** 83 mmHg
- **Density at 20 °C** 0.86 g/cm³
- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.
- **Solubility in / Miscibility with**
- **Water:** Not miscible or difficult to mix
- **Partition coefficient: n-octanol/water:** Not determined.
- **Viscosity:**
- **dynamic:** Not determined.
- **kinematic:** Not determined.
- **Other information** No further relevant information available.
- **Particle characteristics** Not applicable.
- **Physical state** Liquid

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10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Conditions to be avoided:** No decomposition if used and stored according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** Heat, flames and sparks.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Carbon dioxide
- **Additional information:** -

11 Toxicological Information

- **Information on toxicological effects**
 - **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.
- **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 respiratory irritation. 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.

12 Ecological Information

· **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)

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· Persistence and degradability

78-93-3 butanone

Biodegradation 98 % /28d (not defined) (OECD 301D)

· Behaviour in environmental systems:

· **Bioaccumulative potential** No further relevant information available.

· **Mobility in soil** No further relevant information available.

· Additional ecological information:

· **General notes:**

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

· Results of PBT and vPvB assessment

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· Waste treatment methods

· **Recommendation**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· Uncleaned packagings:

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

14 Transport information

· UN-Number

· **ADG, IMDG, IATA**

UN1193

· UN proper shipping name

· **ADG**

1193 ETHYL METHYL KETONE (METHYL ETHYL KETONE)

· **IMDG, IATA**

ETHYL METHYL KETONE (METHYL ETHYL KETONE)

· Transport hazard class(es)

· **ADG**



· **Class**

3 (F1) Flammable liquids.

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· Label	3
· IMDG, IATA	
	
· Class	3 Flammable liquids.
· Label	3
· Packing group	
· ADG, IMDG, IATA	II
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Warning: Flammable liquids.
· Kehler Number:	33
· EMS Number:	F-E,S-D
· Stowage Category	B
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	-
· ADG	
· 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

15 Regulatory information

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

· Australian Inventory of Industrial Chemicals

All ingredients are listed.

· Australia: Priority Existing Chemicals

None of the ingredients is listed.

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- **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 (EU) No 649/2012**

None of the ingredients are included.

- **National regulations**

The product is subject to classification in accordance with the prevailing version of the regulations on hazardous materials.

- **Other regulations, limitations and prohibitive regulations**

· **AICS - Australian Inventory of Chemical Substances**

All ingredients are listed.

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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.

H335 May cause respiratory irritation.

H336 May cause drowsiness or dizziness.

- **Abbreviations and acronyms:**

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

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

Flammable liquids – Category 2: Flammable liquids – Category 2

Eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A

Specific target organ toxicity (single exposure) – Category 3: Specific target organ toxicity (single exposure) – Category 3

- *** Data compared to the previous version altered.**