



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

Printing date 01.08.2022

Version number 3

Revision: 01.08.2022

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

· **1.1 Product identifier**

· Trade name: **Palaferm insulation**

· **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](mailto: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.

· **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 statements**

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

· **Precautionary statements**

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P280 Wear protective gloves / eye 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.

· **2.3 Other hazards -**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

**SECTION 3: Composition/information on ingredients**

· **3.2 Mixtures**

· **Description:** -

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**· Dangerous components:**

CAS: 64-17-5 EINECS: 200-578-6 Reg.nr.: 2119457610-43-xxxx	ethanol ----- Flam. Liq. 2, H225 Eye Irrit. 2, H319 Specific concentration limit: Eye Irrit. 2; H319: C ≥ 50%	≥50-≤75%
CAS: 10035-04-8 EC number: 600-075-5 Reg.nr.: 01-2119494219-28-XXXX	calcium chloride, dihydrate ----- Eye Irrit. 2, H319	≥10-≤25%
CAS: 78-93-3 EINECS: 201-159-0	butanone ----- Flam. Liq. 2, H225 Eye Irrit. 2, H319; STOT SE 3, H336 EUH066	≥0-<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.
  - **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**  
CO<sub>2</sub>, 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.
- **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.
- **6.2 Environmental precautions:**  
Prevent material from reaching sewage system, holes and cellars.  
Dilute with much water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).

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**6.4 Reference to other sections**

No dangerous materials are released.

See Section 8 for information on personal protection equipment.

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**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:**

**64-17-5 ethanol**

WEL (Great Britain) Long-term value: 1920 mg/m<sup>3</sup>, 1000 ppm

**78-93-3 butanone**

WEL (Great Britain) Short-term value: 899 mg/m<sup>3</sup>, 300 ppm  
Long-term value: 600 mg/m<sup>3</sup>, 200 ppm  
Sk, BMGV

IOELV (European Union) Short-term value: 900 mg/m<sup>3</sup>, 300 ppm  
Long-term value: 600 mg/m<sup>3</sup>, 200 ppm

**DNELs**

**64-17-5 ethanol**

Oral	general population, long term, systemic	87 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	343 mg/Kg/d (not defined)
	general population, long term, systemic	206 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	950 mg/m <sup>3</sup> (not defined)
	general population, long term, systemic	114 mg/m <sup>3</sup> (not defined)

**10035-04-8 calcium chloride, dihydrate**

Inhalative	worker industrial, acute, local	10 mg/m <sup>3</sup> (not defined)
	worker industrial, long term, local	5 mg/m <sup>3</sup> (not defined)
	general population, acute, local	5 mg/m <sup>3</sup> (not defined)
	general population, long term, local	2.5 mg/m <sup>3</sup> (not defined)

**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)

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Inhalative	worker industrial, long term, systemic	600 mg/m <sup>3</sup> (not defined)
	general population, long term, systemic	106 mg/m <sup>3</sup> (not defined)

· **PNECs**

**64-17-5 ethanol**

freshwater	0.96 mg/l (not defined)
marine water	0.79 mg/l (not defined)
sewage treatment plant	580 mg/l (not defined)
sediment, dry weight, freshwater	3.6 mg/Kg (not defined)
sediment, dry weight, marine water	2.9 mg/Kg (not defined)
soil, dry weight	0.63 mg/Kg (not defined)

· **Ingredients with biological limit values:**

**78-93-3 butanone**

BMGV (Great Britain)	70 µmol/L Medium: urine Sampling time: post shift Parameter: butan-2-one
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· **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**

Wash hands during breaks and at the end of the work.

· **Breathing equipment:** Not necessary if room is well-ventilated.

· **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 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/face protection** Tightly sealed safety glasses.

· **Body protection:** Light weight protective clothing

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**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** 78 °C
- **Flammability** Not applicable.
- **Lower and upper explosion limit**
  - **Lower:** 3.5 Vol %
  - **Upper:** 15.0 Vol %
- **Flash point:** 14 °C
- **Ignition temperature:** 400 °C
- **Decomposition temperature:** Not determined.

**· SADT**

- **pH** Not determined.
- **Viscosity:**
  - **Kinematic viscosity** Not determined.
  - **dynamic:** Not determined.
- **Solubility**
  - **Water:** Fully miscible
- **Partition coefficient n-octanol/water (log value)** Not determined.
- **Steam pressure at 20 °C:** 57 hPa
- **Density and/or relative density**
  - **Density at 20 °C** 0.930 g/cm<sup>3</sup>
  - **Relative density** Not determined.
  - **Vapour density** Not determined.

**· 9.2 Other information**

No further relevant information available.

**· Appearance:**

- **Form:** Liquid

**· 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** 679.0 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

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· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	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

**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:**

**64-17-5 ethanol**

Oral	LD50	10,470 mg/kg (rat) (OECD 401)
Inhalative	LC50/4 h	124.7 mg/l (rat) (OECD 403)

**10035-04-8 calcium chloride, dihydrate**

Oral	LD50	2,301 mg/kg (rat) (OECD 401)
Dermal	LD50	>5,000 mg/kg (rabbit)

**78-93-3 butanone**

Oral	LD50	2,193 mg/kg (rat) (OECD 423)
Dermal	LD50	8,100 mg/kg (rabbit) (OECD 402)

- **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** Based on available data, the classification criteria are not met.
- **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.

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· **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

**SECTION 12: Ecological information**

· **12.1 Toxicity**

· **Aquatic toxicity:**

**64-17-5 ethanol**

LC50/96h	14,200 mg/l (fish)
ErC50 / 72 h	275 mg/l (algae) (OECD 201)
EC50/96h	129,000 mg/L (fish)
LC50/48h	5,012 mg/L (daphnia)
ErC10/72h	11.5 mg/L (algae) (OECD 201)
NOEC 5d	250 mg/L (fish) (OECD 212)
NOEC 10d	9.6 mg/L (daphnia)

**10035-04-8 calcium chloride, dihydrate**

EC50/48h	144 mg/l (daphnia)
LC50/96h	10.65 mg/l (fish)
IC 50/ 72h	3.13 mg/l (algae)

**78-93-3 butanone**

EC50/48h	308 mg/l (daphnia) (OECD 202)
LC50/96h	2,993 mg/l (fish) (OECD 203)
ErC50 / 72 h	1,220 mg/l (algae) (OECD 201)
NOEC / 96h	1,170 mg/l (fish) (OECD 203)
NOEC / 48h	68 mg/l (daphnia) (OECD 202)
ErC10/72h	1,020 mg/L (algae) (OECD 201)

· **12.2 Persistence and degradability**

**64-17-5 ethanol**

Biodegradation	84 % /20d (not defined)
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**78-93-3 butanone**

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

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**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.

· **Waste disposal key number: 55503**

· **Uncleaned packagings:**

· **Recommendation:**

Disposal must be made according to official regulations.

Non contaminated packagings can be used for recycling.

· **Recommended cleaning agent: Water, if necessary with cleaning agent.**

**SECTION 14: Transport information**

· **14.1 UN number or ID number**

· **ADR, IMDG, IATA**

UN1170

· **14.2 UN proper shipping name**

· **ADR**

· **IMDG**

· **IATA**

1170 ETHANOL (ETHYL ALCOHOL) solution

ETHANOL (ETHYL ALCOHOL) solution

ETHANOL solution

· **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:**

3-06

· **Stowage Category**

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· <b>14.7 Maritime transport in bulk according to IMO instruments</b>	Not applicable.
· <b>Transport/Additional information:</b>	-
· <b>ADR</b>	
· <b>Limited quantities (LQ)</b>	1L
· <b>Excepted quantities (EQ)</b>	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>Transport category</b>	2
· <b>Tunnel restriction code</b>	D/E
· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	1L
· <b>Excepted quantities (EQ)</b>	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>UN "Model Regulation":</b>	UN 1170 ETHANOL (ETHYL ALCOHOL) 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.

· **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.

· **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)

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*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*  
*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.**

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