



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

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
- **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 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/sparks/open flames/hot surfaces. - No smoking.
P241 Use explosion-proof electrical/ventilating/lighting/equipment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P240 Ground/bond container and receiving equipment.
P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
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.

(Contd. on page 2)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Palaferm insulation

· **vPvB:** Not applicable.

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**

· **Description:** -

· **Dangerous components:**

CAS: 64-17-5 EINECS: 200-578-6 Reg.nr.: 2119457610-43-xxxx	ethanol Flam. Liq. 2, H225	50-75%
CAS: 10035-04-8 EINECS: 233-140-8	calcium chloride, dihydrate Acute Tox. 4, H302; Eye Irrit. 2, H319	10-25%

· **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.

· **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.

· **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.

· **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).

(Contd. on page 3)

GB



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Palaferm insulation

(Contd. of page 2)

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

Additional information about design of technical systems: No further data; see item 7.

8.1 Control parameters

Components with critical values that require monitoring at the workplace:

64-17-5 ethanol

OES () Long-term value: 1920 mg/m³, 1000 ppm

DNELs

64-17-5 ethanol

Oral	ge.pop., l.te, syst.	87 mg/Kg (nd)
Dermal	worker profess., l.te., syst.	343 mg/Kg/d (nd)
	ge.pop., acu., local	950 mg/Kg/d (nd)
	ge.pop., l.te, syst.	206 mg/Kg/d (nd)
Inhalative	worker profess., acute, local	1900 mg/m ³ (nd)
	worker profess., l.te., syst.	1900 mg/m ³ (nd)
	ge.pop., acu., local	950 mg/m ³ (nd)
	ge.pop., l.te, syst.	114 mg/m ³ (nd)

PNECs

64-17-5 ethanol

freshwater	0.96 mg/l (nd)
marine water	0.79 mg/l (nd)
STP	580 mg/l (nd)
sedim., dw, fre.wat.	3.6 mg/Kg (nd)
soil,dw	0.63 mg/Kg (nd)

(Contd. on page 4)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Palaferm insulation

(Contd. of page 3)

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

· **8.2 Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures**

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

· **Breathing equipment:** Not required.

· **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.

· **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:** not absolutely necessary

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

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· **Form:** Liquid

· **Colour:** Colourless

· **Smell:** Alcohol-like

· **Odour threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· **Melting point/Melting range:** Not determined

· **Boiling point/Boiling range:** 78 °C

· **Flash point:** 14 °C

· **Inflammability (solid, gaseous)** Not applicable.

· **Ignition temperature:** 400 °C

· **Decomposition temperature:** Not determined.

(Contd. on page 5)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Palaferm insulation

(Contd. of page 4)

· Self-inflammability:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive. However, formation of explosive air/vapour mixtures is possible.
· Critical values for explosion:	
· Lower:	3.5 Vol %
· Upper:	15.0 Vol %
· Steam pressure at 20 °C:	57 hPa
· Density at 20 °C	0.930 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with	
· Water:	Fully miscible
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
· dynamic:	Not determined.
· kinematic:	Not determined.
· Solvent content:	
· Water:	12.9 %
· VOC EU	679.0 g/l
· Solids content:	22.8 %
· 9.2 Other information	No further relevant information available.

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 toxicological effects**
 - **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	6200 mg/kg (rat)
Inhalative	LC50/4 h	95.6 mg/l (rat)

(Contd. on page 6)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Palaferm insulation

(Contd. of page 5)

10035-04-8 calcium chloride, dihydrate

Oral	LD50	1000 mg/kg (rat) 500 - 1000 mg/kg (rabbit)
Dermal	LD50	2630 mg/kg (rat)

- **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.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - **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.

SECTION 12: Ecological information

- **12.1 Toxicity**
 - **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 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.
- **12.5 Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **12.6 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.
 - **Waste disposal key number:** 55503

· **European waste catalogue**

18 01 06 | chemicals consisting of or containing dangerous substances

- **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.

(Contd. on page 7)



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

Printing date 03.06.2017

Version number 3



Revision: 03.06.2017

Trade name: Palaferm insulation

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

(Contd. of page 6)

SECTION 14: Transport information

· 14.1 UN-Number · ADR, IMDG, IATA	1170
· 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 · Kemler Number: · EMS Number:	Warning: Flammable liquids. 33 F-E,S-D
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	-
· UN "Model Regulation":	UN1170, ETHANOL (ETHYL ALCOHOL) solution, 3, II

GB
(Contd. on page 8)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Palaferm insulation

(Contd. of page 7)

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
 - **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 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.
 - H302 Harmful if swallowed.
 - H319 Causes serious eye irritation.
- **Abbreviations and acronyms:**
 - ADR: Accord européen sur le transport 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
 - Acute Tox. 4: Acute toxicity – Category 4
 - Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
- *** Data compared to the previous version altered.**

GB