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Safety Data Sheet acc. to OSHA HCS

Printing date 11/26/2025

Reviewed on 11/26/2025

Tel.: +49 (0)800 4372522

1 Identification

- · Product identifier
 - · Trade name: Palaferm insulation

- · Application of the substance / the mixture Auxiliary for manufacture of dental prothesis
- · Details of the supplier of the safety data sheet
 - Manufacturer/Supplier:

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Information department:

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545 e-mail: customer.servicehkna@kulzer-dental.com

· Emergency telephone number:

Emergency CONTACT (24-Hour-Number)
ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard(s) identification

Classification of the substance or mixture

Flammable Liquids 2 H225 Highly flammable liquid and vapor.

Eye Irritation 2A H319 Causes serious eye irritation.

- · Label elements
 - GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms





GHS02 GHS07

- · Signal word Danger
- · Hazard statements

Highly flammable liquid and vapor.

Causes serious eye irritation.

· Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Wear protective gloves / eye protection.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

- Classification system
 - · NFPA ratings for USA (scale 0-4)



Health = 2Fire = 3Reactivity = 0

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· HMIS-Ratings (Scale 0-4)

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HEALTH 2
FIRE 3
REACTIVITY 0

Health = 2 Fire = 3 Reactivity = 0

- · Results of PBT and vPvB assessment
 - · **PBT:** Not applicable. · **vPvB:** Not applicable.

3 Composition/information on ingredients

- · Chemical characterization: Mixtures
 - · Description: -

	Bedonpaloni		
		us components:	
Γ	64-17-5		<i>≥50-≤</i> 75%
		Flammable Liquids 2, H225 Specific concentration limit: Eye Irrit. 2; H319: C ≥ 50 %	
Γ	10035-04-8	calcium chloride, dihydrate	≥10-≤25%
L		Eye Irritation 2A, H319	

Additional information For the wording of the listed hazard phrases refer to section 16.

4 First-aid measures

- · Description of first aid measures
 - · After inhalation Supply fresh air; consult doctor in case of complaints.
 - · After skin contact Immediately wash with water and soap and rinse thoroughly.
 - · After eye contact Rinse opened eye for several minutes under running water. Then consult a doctor.
 - · After swallowing

Rinse out mouth and then drink plenty of water.

If symptoms persist 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

- Extinguishing media
 - Suitable extinguishing agents

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam

- · Special hazards arising from the substance or mixture Can form explosive gas-air mixtures.
- Advice for firefighters
 - · Protective equipment: No special measures required.

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· Additional information -

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6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures
- Wear protective equipment. Keep unprotected persons away.

Avoid contact with eyes and skin.

Environmental precautions:

Prevent seepage into sewage system, workpits and cellars.

Dilute with plenty of water.

Methods and material for containment and cleaning up:

Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).

Reference to other sections

No dangerous substances are released.

See Section 8 for information on personal protection equipment.

· Protective Action Criteria for Chemicals

· PAC-1:		
64-17-5		1,800 ppm
	calcium chloride, dihydrate	16 mg/m³
78-93-3	78-93-3 butanone 200 pp	
PAC-2:		
64-17-5		3300* ppm
	calcium chloride, dihydrate	170 mg/m³
78-93-3	78-93-3 butanone 270	
PAC-3:		
64-17-5	ethanol	15000* ppm
	calcium chloride, dihydrate	1,100 mg/m³
78-93-3	butanone	4000* ppm

7 Handling and storage

- · Handling
 - · Precautions for safe handling Keep receptacles tightly sealed.
 - Information about protection against explosions and fires:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- Conditions for safe storage, including any incompatibilities
 - Storage
 - Requirements to be met by storerooms and receptacles: Store in a 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 receptacles.

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

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8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see section 7.
- · Control parameters
 - · Components with limit values that require monitoring at the workplace:

The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.

At this time, the remaining constituent has no known exposure limits.

61-	17-	.5 c	th	an	~ 1

PEL Long-term value: 1900 mg/m³, 1000 ppm REL Long-term value: 1900 mg/m³, 1000 ppm TLV Short-term value: 1000 ppm

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

· Exposure controls

- Personal protective equipment
 - General protective and hygienic measures Wash hands before breaks and at the end of work.
 - · Breathing equipment: Not necessary if room is well-ventilated.
 - · 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: Tightly sealed goggles.
- · Body protection: Light weight protective clothing

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9 Physical and chemical properti	ies
Information on basic physical and che General Information Appearance: Form: Color: Odor:	emical properties Liquid Colorless Alcohol-like
· Odor threshold:	Not determined.
· pH-value:	Not determined.
Change in condition Melting point/Melting range: Boiling point/Boiling range:	undetermined 78 °C (172.4 °F)
· Flash point:	14.5 °C (58.1 °F)
· Flammability (solid, gaseous)	Not applicable.
· Auto igniting:	400 °C (752 °F)
Decomposition temperature:	Not determined.
· Ignition temperature:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
· Explosion limits: · Lower: · Upper:	3.5 Vol % 15.0 Vol %
· Vapor pressure at 20 °C (68 °F):	57 hPa (42.8 mm Hg)
Density at 20 °C (68 °F): Relative density Vapor density Evaporation rate	0.930 g/cm³ (7.76085 lbs/gal) Not determined. Not determined. Not determined.
· Solubility in / Miscibility with · Water:	Fully miscible
· Partition coefficient (n-octanol/wat	ter): Not determined.
· Viscosity: · dynamic: · kinematic:	Not determined. Not determined.
· Other information	No further relevant information available.

10 Stability and reactivity

- Reactivity No further relevant information available.
 Possibility of hazardous reactions No dangerous reactions known
 Conditions to avoid No further relevant information available.
- Incompatible materials: No further relevant information available.

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· Hazardous decomposition products: none

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11 Toxicological information

- · Information on toxicological effects
 - · Acute toxicity:

· 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)		

- Primary irritant effect:
 - · on the skin: No irritant effect.
 - · on the eye: No irritating effect.
- · Sensitization: No sensitizing effects known.
- Additional toxicological information:
 - · Carcinogenic categories
 - · IARC (International Agency for Research on Cancer)

In its assessment of ethanol, IARC refers to alcoholic beverages, more specifically to the oral route of ingestion. Therefore, this assessment does not apply to this product.

64-17-5 ethanol	1

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

Reproductive toxicity Based on available data, the classification criteria are not met.

12 Ecological information

· Toxicity		
· Aquatic toxicity:		
64-17-5 etha	nol	
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)	
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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)

· Persistence and degradability

64-17-5 ethanol

biodegradability 84 % /20d (not defined)

- Behavior 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 course 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.

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.

· Recommended cleansing agent: Water, if necessary with cleansing agents.

14 Transport information

UN-Number DOT, ADR, IMDG, IATA	UN1170
· UN proper shipping name · DOT · ADR · IMDG · IATA	Ethanol solution 1170 ETHANOL (ETHYL ALCOHOL) solution ETHANOL (ETHYL ALCOHOL) solution ETHANOL solution

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(Contd. of page 7) · Transport hazard class(es) DOT · Class 3 Flammable liquids · Label · ADR · Class 3 (F1) Flammable liquids · Label · IMDG, IATA · Class 3 Flammable liquids · Label · Packing group · DOT, ADR, IMDG, IATA II· Environmental hazards: Marine pollutant: No Warning: Flammable liquids · Special precautions for user · Hazard identification number (Kemler code): 33 F-E,S-D EMS Number: · Stowage Category · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable. · Transport/Additional information: · ADR · Excepted quantities (EQ) Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 · Limited quantities (LQ) 1L Code: E2 Excepted quantities (EQ) Maximum net quantity per inner packaging: 30 ml (Contd. on page 9)

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Maximum net quantity per outer packaging: 500

ml

· UN "Model Regulation": UN 1170 ETHANOL (ETHYL ALCOHOL) SOLUTION,

3, 11

15 Regulatory information

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

· SARA Section 355 (extremely hazardous substances)

None of the ingredients is listed.

· SARA Section 313 (specific toxic chemical listings)

None of the ingredients is listed.

· Hazardous Air Pollutants

None of the ingredients is listed.

· Proposition 65

· Prop 65 - Chemicals known to cause cancer

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

Ethyl alcohol in alcoholic beverages is listed due to its developmental toxicity. This does not apply to this product.

64-17-5 ethanol

· Cancerogenity categories

EPA (Environmental Protection Agency)

78-93-3 butanone

· TLV (Threshold Limit Value)

64-17-5 ethanol

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· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is 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 vapor.

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H319 Causes serious eye irritation.

Date of preparation / last revision 11/26/2025 / -

· Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the ADR: Accord relatit au transport international des marchandises dangereuse International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances (Association Chemical Abstracts Service (division of the American Chemical Substances)

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

LD50: Letnal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Flammable Liquids 2: Flammable liquids - Category 2

Eye Irritation 2A: Serious eye damage/eye irritation - Category 2A

* Data compared to the previous version altered.