



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

Printing date 03.08.2022

Version number 3

Revision: 03.08.2022

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

· **1.1 Product identifier**

· Trade name: **Palaclean**

· **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** Cleaning material/ Detergent

· **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:**

ethyl acetate

· **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.

P261 Avoid breathing mist/vapours/spray.

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.

P337+P313 If eye irritation persists: Get medical advice/attention.

· **Additional information:**

EUH066 Repeated exposure may cause skin dryness or cracking.

· **2.3 Other hazards -**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

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· **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**

· **Description:** -

· **Dangerous components:**

CAS: 141-78-6 EINECS: 205-500-4 Reg.nr.: 01-2119475103-46-xxxx	ethyl acetate	Flam. Liq. 2, H225 Eye Irrit. 2, H319; STOT SE 3, H336 EUH066	>90%
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· **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**

· **General information** Take affected persons out of danger area and instruct to lie down.

· **After inhalation** Supply fresh air; consult doctor in case of symptoms.

· **After skin contact** 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**

Fire-extinguishing powder

Carbon dioxide

Alcohol-resistant foam

· **For safety reasons unsuitable extinguishing agents** Water with a full water jet.

· **5.2 Special hazards arising from the substance or mixture**

Can form explosive gas-air mixtures.

Carbon monoxide (CO)

Carbon dioxide (CO₂)

Formation of toxic gases is possible during heating or in case of fire.

· **5.3 Advice for firefighters**

· **Protective equipment:**

Wear self-contained breathing apparatus.

Wear full protective suit.

· **Additional information** -

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures**

Wear protective equipment. Keep unprotected persons away.

Ensure adequate ventilation

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- Keep away from ignition sources
Use breathing protection against the effects of fumes/dust/aerosol.
Avoid contact with eyes and skin.
- **6.2 Environmental precautions:**
Inform respective authorities in case product reaches water or sewage system.
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).
Dispose of contaminated material as waste according to item 13.
 - **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**
Avoid contact with eyes and skin.
Wear protective equipment. Keep unprotected persons away.
Keep containers tightly sealed.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
 - **Information about protection against explosions and fires:**
Fumes can combine with air to form an explosive mixture.
Use only in explosion-proof area.
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:**
Provide solvent resistant, sealed floor.
Store in cool location.
 - **Information about storage in one common storage facility:** Store away from foodstuffs.
 - **Further information about storage conditions:**
Store container in a well ventilated position.
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:**

141-78-6 ethyl acetate

OEL (Ireland)	Short-term value: 1468 mg/m ³ , 400 ppm Long-term value: 734 mg/m ³ , 200 ppm IOELV
IOELV (European Union)	Short-term value: 1468 mg/m ³ , 400 ppm Long-term value: 734 mg/m ³ , 200 ppm

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· DNELs

141-78-6 ethyl acetate

Oral	general population, long term, systemic	4.5 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	63 mg/Kg/d (not defined)
	general population, long term, systemic	37 mg/Kg/d (not defined)
Inhalative	worker industrial, acute, systemic	1,468 mg/m ³ (not defined)
	worker industrial, acute, local	1,468 mg/m ³ (not defined)
	worker industrial, long term, systemic	734 mg/m ³ (not defined)
	worker industrial, long term, local	734 mg/m ³ (not defined)
	general population, acute, systemic	734 mg/m ³ (not defined)
	general population, acute, local	734 mg/m ³ (not defined)
	general population, long term, systemic	367 mg/m ³ (not defined)
	general population, long term, local	367 mg/m ³ (not defined)

· PNECs

141-78-6 ethyl acetate

freshwater	0.24 mg/l (not defined)
marine water	0.024 mg/l (not defined)
sewage treatment plant	650 mg/l (not defined)
sediment, dry weight, freshwater	1.15 mg/Kg (not defined)
sediment, dry weight, marine water	0.115 mg/Kg (not defined)
soil, dry weight	0.148 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 item 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:

Use breathing protection only when aerosol or mist is formed.

Filter A/P2.

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

Recommended thickness of the material: ≥ 0.5 mm

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/face protection** Tightly sealed safety glasses.
- **Body protection:** Solvent resistant protective clothing
- **Environmental exposure controls**
Do not allow to enter drainage system, surface or ground water.
Do not allow to enter the ground/soil.

SECTION 9: Physical and chemical properties

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

· **General Information**

- | | |
|---|------------------------------------|
| · Physical state | Fluid |
| · Colour: | Colourless |
| · Smell: | Fruit-like |
| · Odour threshold: | Not determined. |
| · Melting point/freezing point: | Not determined |
| · Boiling point or initial boiling point and boiling range | 77 °C (141-78-6 ethyl acetate) |
| · Flammability | Not applicable. |
| · Lower and upper explosion limit | |
| · Lower: | 2.1 Vol % |
| · Upper: | 11.5 Vol % |
| · Flash point: | -4 °C (141-78-6 ethyl acetate) |
| · Ignition temperature: | 460 °C |
| · Decomposition temperature: | Not determined. |
| · SADT | |
| · pH | Mixture is non-soluble (in water). |
| · Viscosity: | |
| · Kinematic viscosity | Not determined. |
| · dynamic at 20 °C: | 0.44 mPas |
| · Solubility | |
| · Water at 20 °C: | 61 g/l |
| · Partition coefficient n-octanol/water (log value) | 0.6 log POW |
| · Steam pressure at 20 °C: | 102 hPa |
| · Density and/or relative density | |
| · Density at 20 °C | 0.901 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.

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· 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
· 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** 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:** Strong oxidizers
- **10.6 Hazardous decomposition products:**
Ethanoic acid
In case of fire the following can be released:
Carbon monoxide and 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:**

141-78-6 ethyl acetate

Dermal	LD50	>20,000 mg/kg (rabbit)
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- **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.

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- **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**

None of the ingredients is listed.

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

141-78-6 ethyl acetate

LC50/96h	230 mg/l (fish)
NOEC / 21d	2.4 mg/l (daphnia) (OECD 211)
NOEC / 72h	>100 mg/l (algae) (OECD 201)

· **12.2 Persistence and degradability**

Easily biodegradable

141-78-6 ethyl acetate

Biodegradation	69 % /20d (not defined)
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· **12.3 Bioaccumulative potential**

141-78-6 ethyl acetate

Bloconcentration factor (BCF)	30 (not defined)
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· **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.

· **European waste catalogue**

18 01 06*	chemicals consisting of or containing hazardous substances
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· **Uncleaned packagings:**

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

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SECTION 14: Transport information

· 14.1 UN number or ID number · ADR, IMDG, IATA	UN1173
· 14.2 UN proper shipping name · ADR · IMDG, IATA	1173 ETHYL ACETATE solution ETHYL ACETATE 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: · Stowage Category	Warning: Flammable liquids. 33 F-E,S-D B
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	-
· ADR · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category · Tunnel restriction code	2 D/E
· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging:

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500 ml

· **UN "Model Regulation":**

UN 1173 ETHYL ACETATE 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

· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

· **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**

None of the ingredients is listed.

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

None of the ingredients is listed.

· **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:** 03.08.2022

· **Version number of previous version:** 2

· **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

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)

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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.**

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