

according to Regulation (EU) 2020/878
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Pro Die Hardener / Pro Die Spacer

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

- 1.1. Product identifier**
Product form: Mixture
Product name: Pro Die Hardener / Pro Die Spacer
UFI: -
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**
Relevant identified uses: Manufacturing of dental prosthesis in dental laboratories
Uses advised against: Do not use outside of the dental laboratory.
- 1.3. Details of the supplier of the safety data sheet**
Manufacturer/Supplier: al dente Dentalprodukte GmbH
Street / mailbox: Borsigstr. 1
Country code / postal code / city: D - 38644 Goslar
Phone: 0 53 21 / 80031
Fax: 0 53 21 / 50881
E-mail / Website: info@aldente.de / www.aldente.de
Information department: al dente Dentalprodukte GmbH
- 1.4. Emergency telephone number**
al dente Dentalprodukte GmbH: +49 (0) 53 21 / 80031 (Mo-Fr 8:00-16:00)

SECTION 2: Hazards identification

- 2.1. Classification of the substance or mixture**
Classification according to Regulation (EC) No. 1272/2008 [CLP]
 Flammable liquids, Category 2, H225
 Serious eye damage/eye irritation, Category 2, H319
 Specific target organ toxicity — Single exposure, Category 3, Narcosis, H336
 Full text of H statements: see section 16.
Adverse physicochemical, human health and environmental effects
 Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness.
- 2.2. Label elements**
Labelling according to Regulation (EC) No. 1272/2008 [CLP]
Hazard pictograms (CLP):
- 
 GHS02


 GHS07
- Signal word (CLP):** Danger
Hazard-determining components for labelling: Ethyl acetate
- Hazard statements (CLP):**
 H225 - Highly flammable liquid and vapour
 H319 - Causes serious eye irritation
 H336 - May cause drowsiness or dizziness
- Precautionary statements (CLP):**
 P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking
 P233 - Keep container tightly closed
 P261 - Avoid breathing vapours/spray
 P280 - Wear protective gloves, protective clothing, eye protection
 P337+P313 - If eye irritation persists: Get medical advice/attention
 P403+P235 - Store in a well-ventilated place. Keep cool

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Pro Die Hardener / Pro Die Spacer**EUH phrases:**

EUH066 - Repeated exposure may cause skin dryness or cracking

2.3. Other hazards**Results of PBT and vPvB assessment****PBT:**

Not applicable

vPvB:

Not applicable

SECTION 3: Composition/information on ingredients**3.1. Substances:**

Not applicable

3.2. Mixtures**Components:**

(CAS no) 141-78-6	Ethyl acetate	75 - 95 %
(EC no) 205-500-4	Flam. Liq. 2, H225	
(EC Index no) 607-022-00-5	Eye Irrit. 2, H319	
(REACH no) 01-2119475103-46-xxxx	STOT SE 3, H336	

Full text of H statements: see section 16.

SECTION 4: First aid measures**4.1. Description of first aid measures****First-aid measures general:**

Call a doctor if you feel unwell. If possible show him this sheet. Failing this, show him the packaging or label. Never give anything by mouth to an unconscious person. Place the affected person in the recovery position.

First-aid measures after inhalation:

Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical advice/attention if you feel unwell.

First-aid measures after skin contact:

Take off contaminated clothing. Wash with plenty of soap and water.

First-aid measures after eye contact:

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion:

Rinse mouth. Drink water as a precaution. Do NOT induce vomiting.

4.2. Most important symptoms and effects, both acute and delayed**Symptoms/injuries after inhalation:**

May cause drowsiness or dizziness.

Symptoms/injuries after eye contact:

Causes serious eye irritation.

Other symptoms/injuries:

Headache. Dizziness. Drowsiness. Nausea. Vomiting. Repeated exposure may cause skin dryness or cracking.

4.3. Indication of any immediate medical attention and special treatment needed:

Treat symptomatically.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media:**

Dry extinguishing powder. Foam. Carbon dioxide. Water spray.

Unsuitable extinguishing media:

Do not use a heavy water stream.

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5.2. Special hazards arising from the substance or mixture

Fire hazard:	Highly flammable liquid and vapour.
Explosion hazard:	May form flammable/explosive vapour-air mixture.
Hazardous decomposition products in case of fire:	Toxic fumes may be released. Carbon monoxide. Carbon dioxide.
5.3. Advice for firefighters	
Firefighting instructions:	Use water spray or fog for cooling exposed containers. Do not dispose of fire-fighting water in the environment.
Protection during firefighting:	Use a self-contained breathing apparatus and also a protective suit.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures:	Provide adequate ventilation. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking. Stop leak if safe to do so. Use personal protective equipment as required. Avoid contact with skin and eyes. Do not breathe vapour/aerosol.
For non-emergency personnel	
Emergency procedures:	Evacuate unnecessary personnel.
For emergency responders	
Protective equipment:	Wear personal protective equipment. Use self-contained breathing apparatus.
6.2. Environmental precautions:	Prevent entry to sewers and public waters.
6.3. Methods and material for containment and cleaning up:	Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Dispose of in accordance with relevant local regulations.
6.4. Reference to other sections:	Concerning personal protective equipment to use, see section 8. Concerning disposal elimination after cleaning, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed:	Handle empty containers with care because residual vapours are flammable.
Precautions for safe handling:	Provide good ventilation in process area to prevent formation of vapour. Remove ignition sources. No open flames. No smoking. Use only non-sparking tools. Take precautionary measures against static discharge. Wear personal protective clothing. Do not breathe vapour/aerosol. Avoid contact with skin and eyes.
Information on fire and explosion protection:	May form flammable/explosive vapour-air mixture.

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Pro Die Hardener / Pro Die Spacer**Hygiene measures:**

Handle in accordance with good industrial hygiene and safety procedures. When using do not eat, drink or smoke. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Take off contaminated clothing and wash it before reuse. Contaminated work clothing should not be allowed out of the workplace.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and containers****Technical measures:**

Proper grounding procedures to avoid static electricity should be followed. Ground/bond container and receiving equipment. Use explosion-proof electrical, ventilating, lighting equipment.

Storage temperature:

< 30 °C

Storage conditions:

Store in original container. Keep container tightly closed. Store in a dry, cool and well-ventilated place. Protect from sunlight. Keep in fireproof place. Store locked up. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Prohibitions on mixed storage:

Keep away from food, drink and animal feedingstuffs.

7.3. Specific end use(s):

No additional information available

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****Components with critical values that require monitoring at the workplace:****Ethyl acetate (141-78-6)**

EU	Local name	Ethyl acetate
EU	IOELV TWA (mg/m ³)	734 mg/m ³
EU	IOELV TWA (ppm)	200 ppm
EU	IOELV STEL (mg/m ³)	1468 mg/m ³
EU	IOELV STEL (ppm)	400 ppm
Ireland	Local name	Ethyl acetate
Ireland	OEL (8 hours ref) (ppm)	200 ppm
Ireland	OEL (8 hours ref) (mg/m ³)	734 mg/m ³
Ireland	OEL (15 min ref) (ppm)	400 ppm
Ireland	OEL (15 min ref) (mg/m ³)	1468 mg/m ³
Ireland	Notes	IOELV
Malta	Local name	Ethyl acetate
Malta	OEL 8 hours (mg/m ³)	734 mg/m ³
Malta	OEL 8 hours (ppm)	200 ppm
Malta	OEL STEL (mg/m ³)	1468 mg/m ³
Malta	OEL STEL (ppm)	400 ppm

Ethyl acetate (141-78-6)**DNEL/DMEL (Workers)**

Acute - systemic effects, inhalation	1468 mg/m ³
Acute - local effects, inhalation	1468 mg/m ³
Long-term - systemic effects, inhalation	734 mg/m ³
Long-term - local effects, inhalation	734 mg/m ³
Long-term - systemic effects, dermal	63 mg/kg bodyweight/day

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DNEL/DMEL (General population)	
Acute - systemic effects, inhalation	734 mg/m ³
Acute - local effects, inhalation	734 mg/m ³
Long-term - systemic effects, oral	4.5 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	367 mg/m ³
Long-term - systemic effects, dermal	37 mg/kg bodyweight/day
Long-term - local effects, inhalation	367 mg/m ³
PNEC (Water)	
PNEC aqua (freshwater)	0.24 mg/l
PNEC aqua (marine water)	0.024 mg/l
PNEC aqua (intermittent, freshwater)	1.65 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	1.15 mg/kg dwt
PNEC sediment (marine water)	0.115 mg/kg dwt
PNEC (Soil)	
PNEC soil	0.148 mg/kg dwt
PNEC (Oral)	
PNEC oral (secondary poisoning)	200 mg/kg food
PNEC (STP)	
PNEC sewage treatment plant	650 mg/l

8.2. Exposure controls**Appropriate engineering controls:**

Provide local exhaust or general room ventilation to minimize vapour concentrations.

Personal protective equipment**Eye protection:**

Wear safety glasses (EN 166).

Hand protection:Wear suitable gloves (EN 374). Butyl rubber, ≥ 0.5 mm. The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed. Penetration time (min.): ≥ 60 min**Skin and body protection:**

Wear suitable protective clothing. Flame retardant antistatic protective clothing.

Respiratory protection:

Where exposure through inhalation may occur from use, respiratory protection equipment is recommended. Breathing apparatus with filter type A.

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties****Physical state:**

Liquid

Colour:

Pro Die Hardener: Transparent

Pro Die Spacer: Transparent or coloured

Odour:

No data available

Melting point/Freezing point:

No data available

Boiling point or initial boiling point and boiling range:

No data available

Flammability:

Highly flammable liquid and vapour

Lower and upper explosion limit:

No data available

Flash point:

No data available

Auto-ignition temperature:

No data available

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Decomposition temperature:	No data available
pH:	No data available
Kinematic viscosity:	No data available
Solubility:	No data available
Partition coefficient n-octanol/water (log value):	Not applicable
Vapour pressure:	No data available
Density and/or relative density:	No data available
Relative vapour density:	No data available
Particle characteristics:	Not applicable

9.2. Other information

Explosive properties:	May form flammable/explosive vapour-air mixture
Oxidising properties:	No oxidising properties

SECTION 10: Stability and reactivity

10.1. Reactivity:	Highly flammable liquid and vapour. May form flammable/explosive vapour-air mixture.
10.2. Chemical stability:	Stable under use and storage conditions as recommended in section 7.
10.3. Possibility of hazardous reactions:	The substance can react with oxidizing agents.
10.4. Conditions to avoid:	Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition. Prolonged storage above 45 °C.
10.5. Incompatible materials:	Acids. Bases. Oxidizing agents. Peroxides. Amines. Alkali metals. Polymerization initiators. Perchloric acid.
10.6. Hazardous decomposition products:	Acetic acid. Ethanol. In case of fire: Toxic fumes may be released. Carbon dioxide. Carbon monoxide.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

Acute toxicity:	Not classified
	Based on available data, the classification criteria are not met

Ethyl acetate (141-78-6)	
LD50 oral rat:	5620 mg/kg
LD50 dermal rabbit:	> 20000 mg/kg
LC0 inhalation rat:	> 22.5 mg/l/6h

Skin corrosion/irritation:	Not classified
	Based on available data, the classification criteria are not met
Serious eye damage/irritation:	Causes serious eye irritation
Respiratory or skin sensitisation:	Not classified
	Based on available data, the classification criteria are not met
Germ cell mutagenicity:	Not classified
	Based on available data, the classification criteria are not met
Carcinogenicity:	Not classified

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Based on available data, the classification criteria are not met

Specific target organ toxicity (single exposure):

May cause drowsiness or dizziness

Specific target organ toxicity (repeated exposure):

Not classified

Based on available data, the classification criteria are not met

Aspiration hazard:

Not classified

Based on available data, the classification criteria are not met

11.2. Information on other hazards**Potential adverse human health effects and symptoms:**

Based on available data, the classification criteria are not met

SECTION 12: Ecological information**12.1. Toxicity****Acute aquatic toxicity:**

Not classified

Chronic aquatic toxicity:

Not classified

Ecology - general advice:

Avoid release to the environment. Prevent entry to sewers and public waters.

Ethyl acetate (141-78-6)

LC50 fish: 230 mg/l 96 h, Pimephales promelas

EC50 daphnia: 3090 mg/l 24 h, Daphnia magna

EC10 microorganism: 1650 mg/l 15 min, Photobacterium phosphoreum

NOEC fish: > 75.6 mg/l 32 d, Pimephales promelas

NOEC daphnia: 2.4 mg/l 21 d, Daphnia magna

NOEC algae: > 100 mg/l 72 h, Desmodesmus subspicatus

12.2. Persistence and degradability**Ethyl acetate (141-78-6)**

Persistence and degradability: Readily biodegradable.

Biodegradation: 69 % 20 d

12.3. Bioaccumulative potential**Ethyl acetate (141-78-6)**

Log Pow: 0.68 (25 °C)

Bioaccumulation factor: 30

12.4. Mobility in soil:

No additional information available

12.5. Results of PBT and vPvB assessment**PBT:**

Not applicable

vPvB:

Not applicable

12.6. Endocrine disrupting properties:

No additional information available

12.7. Other adverse effects:

No additional information available

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Regional legislation (waste):**




Dispose in a safe manner in accordance with local/national regulations. The product is to be classified as hazardous waste (waste paints).

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Waste disposal recommendations:	Treat contaminated packaging like the product itself.
Waste code - used product:	The waste code number according to the Ordinance on the European Waste Catalogue (AVV) depends on the waste producer and can therefore vary for any given product. The waste code number is therefore to be gleaned separately from each waste producer.
Additional information:	Handle empty containers with care because residual vapours are flammable. Depending on the use. Do not perforate, cut or weld uncleaned containers.

SECTION 14: Transport information

14.1. UN number or ID number	
UN-No. (ADR):	UN 1173
UN-No. (IMDG):	UN 1173
UN-No. (IATA):	UN 1173
14.2. UN proper shipping name	
Proper Shipping Name (ADR):	ETHYL ACETATE
Proper Shipping Name (IMDG):	ETHYL ACETATE
Proper Shipping Name (IATA):	Ethyl acetate
Transport document description (ADR):	UN 1173 ETHYL ACETATE, 3, II, (D/E)
Transport document description (IMDG):	UN 1173 ETHYL ACETATE, 3, II (-4°C c.c.)
Transport document description (IATA):	UN 1173 Ethyl acetate, 3, II
14.3. Transport hazard class(es)	
ADR	
Transport hazard class(es) (ADR):	3
Danger labels (ADR):	3
	
IMDG	
Transport hazard class(es) (IMDG):	3
Danger labels (IMDG):	3
	
IATA	
Transport hazard class(es) (IATA):	3
Danger labels (IATA):	3
	
14.4. Packing group	
Packing group (ADR):	II
Packing group (IMDG):	II
Packing group (IATA):	II

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Dangerous for the environment:	No
Marine pollutant:	No
Other information:	No additional information available

14.6. Special precautions for user

Overland transport	
Classification code (ADR):	F1
Limited quantities (ADR):	1I
Excepted quantities (ADR):	E2
Packing instructions (ADR):	P001, IBC02, R001
Mixed packing provisions (ADR):	MP19
Portable tank and bulk container instructions (ADR):	T4
Portable tank and bulk container special provisions (ADR):	TP1
Tank code (ADR):	LGBF
Vehicle for tank carriage:	FL
Transport category (ADR):	2
Special provisions for carriage - Operation (ADR):	S2, S20
Hazard identification number (Kemler No.):	33
Orange plates:	

33

1173

Tunnel restriction code (ADR):	D/E
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Transport by sea

Limited quantities (IMDG):	1 L
Excepted quantities (IMDG):	E2
Packing instructions (IMDG):	P001
IBC packing instructions (IMDG):	IBC02
Tank instructions (IMDG):	T4
Tank special provisions (IMDG):	TP1
EmS-No. (Fire):	F-E
EmS-No. (Spillage):	S-D
Stowage category (IMDG):	B
Flash point (IMDG):	-4°C c.c.
Properties and observations (IMDG):	Colourless liquid with a fragrant odour. Flashpoint: -4°C c.c. Explosive limits: 2.18% to 11.5%. Immiscible with water.

Air transport

PCA Excepted quantities (IATA):	E2
PCA Limited quantities (IATA):	Y341
PCA limited quantity max net quantity (IATA):	1L
PCA packing instructions (IATA):	353
PCA max net quantity (IATA):	5L
CAO packing instructions (IATA):	364
CAO max net quantity (IATA):	60L
ERG code (IATA):	3L

14.7. Maritime transport in bulk according to IMO instruments:	Not applicable
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SECTION 15: Regulatory information

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

EU-Regulations

Contains no substance on the REACH candidate list.

Contains no REACH Annex XIV substances.

National regulations

No additional information available

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.

The data given here only applies when product used for proper application(s). The product is not sold as suitable for other applications - usage in such may cause risks not mentioned in this sheet. Do not use for other application(s) without seeking advice from manufacturer.

Changes compared to the previous version

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Full text of H- and EUH-statements

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

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CLP:	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DMEL:	Derived Minimal Effect Level
DNEL:	Derived No-Effect Level
EC50:	The effective concentration of substance that causes 50% of the maximum response (Median Effective Concentration)
IATA:	International Air Transport Association
IMDG:	"International Maritime Dangerous Goods Code" for the transport of dangerous goods by sea
LC50:	Lethal Concentration to 50 % of a test population (Median Lethal Concentration)
LD50:	Lethal Dose to 50% of a test population (Median Lethal Dose)
LOAEL:	No Observed Effect Concentration/Level
NOAEC/L:	Organisation for Economic Cooperation and Development
NOEC/L:	Persistent, Bioaccumulative and Toxic substance
OECD:	Predicted No-Effect Concentration
PBT:	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
PNEC:	Safety Data Sheet
REACH:	Sewage Treatment Plant
SDB (SDS):	Unique Formula Identifier
STP:	Very Persistent and Very Bioaccumulative
UFI:	European Agreement concerning the International Carriage of Dangerous Goods by Road

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vPvB:	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
Eye Irrit. 2:	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2:	Flammable liquids, Category 2
STOT SE 3:	Specific target organ toxicity - Single exposure, Category 3, Narcosis