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according to Regulation (EU) 2020/878

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Pro-Seal Wax Sealing

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

company/undertaking

1.1. Product identifier

Product form: Mixture

Product name: Pro-Seal Wax Sealing

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 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 Ethyl acetate

for labelling:

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

EUH phrases: EUH066 - Repeated exposure may cause skin dryness or cracking

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EUH208 - Contains n-butyl methacrylate, methyl methacrylate. May produce an allergic reaction.

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:

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-	STOT SE 3, H336	
XXXX		
(CAS no) 97-88-1	n-butyl methacrylate	< 0.25 %
(EC no) 202-615-1	Flam. Liq. 3, H226	
(REACH no) 01-2119486394-28-	Skin Irrit. 2, H315	
XXXX	Skin Sens. 1, H317	
	Eye Irrit. 2, H319	
	STOT SE 3, H335	
(CAS no) 80-62-6	Methyl methacrylate	< 0.25 %
(EC no) 201-297-1	Flam. Liq. 2, H225	
(REACH no) 01-2119452498-28-	Skin Irrit. 2, H315	
xxxx	Skin Sens. 1, H317	
	STOT SE 3, H335	

Full text of H statements: see section 16.

SECTION 4: First aid measures

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

May cause drowsiness or dizziness.

inhalation:

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Symptoms/injuries after eye

contact:

Causes serious eye irritation.

Other symptoms/injuries: Headache. Dizziness. Drowsiness. Nausea. Vomiting. May produce an

allergic reaction. 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.

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

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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.

protection:

Information on fire and explosion May form flammable/explosive vapour-air mixture.

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.

Conditions for safe storage, including any incompatibilities 7.2.

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.

< 30 °C Storage temperature:

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

Control paral	iletei 5		
Components with critical values that require monitoring at the workplace:			
Ethyl acetate (141-78-6)			
EU	Local name	Ethyl acetate	
EU	IOELV TWA (mg/m³)	734 mg/m³	
EU	IOELV TWA (ppm)	200 ppm	
EU	IOELV STEL (mg/m³)	1468 mg/m³	
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/m³)	734 mg/m³	
Ireland	OEL (15 min ref) (ppm)	400 ppm	
Ireland	OEL (15 min ref) (mg/m³)	1468 mg/m³	
Ireland	Notes	IOELV	
Malta	Local name	Ethyl acetate	
Malta	OEL 8 hours (mg/m³)	734 mg/m³	
Malta	OEL 8 hours (ppm)	200 ppm	

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Malta	OEL STEL (mg/m³)	1468 mg/m³	
Malta	OEL STEL (ppm)	400 ppm	
Methyl methacryla	Methyl methacrylate (80-62-6)		
EU	Local name	methyl methacrylate; methyl 2-methylprop-2- enoate; methyl 2-methylpropenoate	
EU	IOELV TWA (ppm)	50 ppm	
EU	IOELV STEL (ppm)	100 ppm	
Ireland	Local name	Methyl methacrylate	
Ireland	OEL (8 hours ref) (ppm)	50 ppm	
Ireland	OEL (15 min ref) (ppm)	100 ppm	
Ireland	Notes	IOELV, Sens	
Malta	Local name	Methyl methacrylate	
Malta	OEL (8 hours) (ppm)	50 ppm	
Malta	OEL (short-term) (ppm)	100 ppm	

Ethyl acetate (141-78-6)	Ethyl acetate (141-78-6)	
DNEL/DMEL (Workers)		
Acute - systemic effects, inhalation	1468 mg/m ³	
Acute - local effects, inhalation	1468 mg/m³	
Long-term - systemic effects,	734 mg/m³	
inhalation		
Long-term - local effects, inhalation	734 mg/m³	
Long-term - systemic effects,	63 mg/kg bodyweight/day	
dermal		
DNEL/DMEL (General population)		
Acute - systemic effects, inhalation	734 mg/m³	
Acute - local effects, inhalation	734 mg/m³	
Long-term - systemic effects, oral	4.5 mg/kg bodyweight/day	
Long-term - systemic effects,	367 mg/m³	
inhalation		
Long-term - systemic effects,	37 mg/kg bodyweight/day	
dermal		
Long-term - local effects, inhalation	367 mg/m³	
PNEC (Water)		
PNEC aqua (freshwater)	0.24 mg/l	
PNEC aqua (marine water)	0.024 mg/l	
PNEC aqua (intermittent,	1.65 mg/l	
freshwater)		
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:

Personal protective equipment

Eye protection:

Provide local exhaust or general room ventilation to minimize vapour

concentrations.

Wear safety glasses (EN 166).

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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.): \geq 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:

Colour:

Odour:

Melting point/Freezing point:

Boiling point or initial boiling

Liquid

Transparent

No data available

No data available

No data available

point and boiling range:

Flammability: Highly flammable liquid and vapour

Lower and upper explosion limit:

Flash point:

Auto-ignition temperature:

Decomposition temperature:

pH:

Kinematic viscosity:

No data available
No data available
No data available
No data available

Kinematic viscosity:

Solubility:

Partition coefficient n
No data available
No data available
Not applicable

octanol/water (log value):

Vapour pressure:No data availableDensity and/or relative density:No data availableRelative vapour density:No data availableParticle 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 The substance can react with oxidizing agents.

reactions:

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.

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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

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:

Chronic aquatic toxicity:

Not classified

Not classified

Ecology - general advice: Avoid release to the environment. Prevent entry to sewers and public

waters.

	watere.
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

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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

Not applicable PBT: 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).

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 1173 UN-No. (ADR): 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

UN 1173 Ethyl acetate, 3, II

(IATA):

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14.3. Transport hazard class(es)

ADR

Transport hazard class(es) 3

(ADR):

Danger labels (ADR):



3

IMDG

Transport hazard class(es)

(IMDG):

Danger labels (IMDG):



IATA

Transport hazard class(es) 3

(IATA):

Danger labels (IATA): 3



14.4. Packing group

Packing group (ADR): Ш Packing group (IMDG): Ш Packing group (IATA): Ш

14.5. Environmental hazards

Dangerous for the environment: No Marine pollutant: Nο

Other information: No additional information available

TP1

14.6. Special precautions for user

Overland transport

Classification code (ADR): F1 Limited quantities (ADR): 11 **Excepted quantities (ADR):** E2

Packing instructions (ADR): P001, IBC02, R001

Mixed packing provisions (ADR): **MP19** Portable tank and bulk container T4

instructions (ADR):

Portable tank and bulk container

special provisions (ADR):

Tank code (ADR): **LGBF** Vehicle for tank carriage: FL Transport category (ADR): 2 Special provisions for carriage -S2, S20

Operation (ADR):



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Hazard identification number

(Kemler No.): Orange plates: 33

33 1173

Tunnel restriction code (ADR):

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): В

Flash point (IMDG): -4°C c.c.

Properties and observations

Colourless liquid with a fragrant odour. Flashpoint: -4°C c.c. Explosive limits: 2.18% to 11.5%. Immiscible with water. (IMDG):

Air transport

PCA Excepted quantities (IATA): E2 PCA Limited quantities (IATA): Y341 PCA limited quantity max net 1L

quantity (IATA):

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

Not applicable

according to IMO instruments:

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. H226: Flammable liquid and vapour.

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.
H336: May cause drowsiness or dizziness.

EUH066: Repeated exposure may cause skin dryness or cracking.

EUH208: Contains (name of sensitising substance). May produce an allergic reaction.

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

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
Flam. Liq. 3: Flammable liquids, Category 3
Skin Irrit. 2 Skin corrosion/irritation, Category 2
Skin Sens. 1 Sensitisation - Skin, hazard category 1

STOT SE 3: Specific target organ toxicity - Single exposure, Category 3, Respiratory tract irritation

STOT SE 3: Specific target organ toxicity - Single exposure, Category 3, Narcosis