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(amended by regulation (EU) no. 453/2010)

Date of issue 23.04.2015 Date of revision 22.01.16 Valid from 01.01.15 All dental waxes by al dente including: CAD/CAM waxes, Set-up base plates, etc. 01-01ff, 01-3ff, 01-4ff, 01-5ff, 01-6ff, 01-7ff, 02-1ff, 02-2ff, 02-3ff, 02-4ff, 02-5ff, 06-1ff, ZH02-ff, 581-004-011

Version: 3

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Section 1: Identification of the substance/mixture and of the company

1.1 Product Identifier

 Substances: paraffin waxes
 Index-no.: not applicable
 EG-no.: 232-315-6
 CAS-no.: 8002-74-2
 REACH-registration no.: The substance does not require registration according to regulation (EC) no. 1907/2006 (REACH)
 Other means or identification: hydrocarbones

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses: to be used in dental labs exclusively

Uses advised against: should not be used by untrained personnel

1.3 Details of the supplier of the safety data sheet Supplier:

al dente Dentalprodukte GmbH

Street: Am Tobel 15

Address / zip-code / town / country: 88263 Horgenzell Germany

Phone / Fax / Email:

+49 (0) 7504 - 9 70 91-0 / +49 (0) 7504 - 9 70 91-20 / E-Mail: info@aldente.de

1.4 Emergency Telephone Number: +49(0) 171 7508 130

+49 (0) 171 7508 130

Section 2: Hazards identification:

2.1 Classification of the substance or mixture:

Classification according to regulation (EC) no. 1272/2008 (CLP)

This substance does not meet the criteria for classification according to regulation (EC) no. 1272/2008 (CLP).

2.2 Label Elements

Labelling according to regulation (EC) no. 1272/2008 (CLP/GHS)

Hazard pictorams: NONE

Signal word: NONE

Hazardous component(s) for labelling:

Hazard statements:

NONE

Precautionary statements: P210 Keep av

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No

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	smoking.	
P262	Do not get in eyes, on skin, or on clothing.	
P370+	In case of fire:	

P378 Use foam, carbon dioxide, dry powder to extinguish.

Supplemental Hazard information (EU): NONE

2.3 Other Hazards:

Results of PBT and vPvP assessment: PBT not applicable vPvP not applicable

Section 3: Composition/information on ingredients

3.1 Substances

Principal component of the substance:

Substance name: paraffin Index-no.: void EG-no.: 232-315-6 CAS-no.: 8002-74-2

Impurities, stabilizers: none

Substance name: Index-no.: EG-no.: CAS-no.:

3.2 Mixtures none

Description of the mixture: EG-no.: CAS-no.: Index-Nno.: REACH-registration no.: Content ration: % Classification according to regulation (EC) no. 1272/2008 (CLP) none

(Full text of H- and EUH-phrases: see SECTION 16)

Section 4: First aid measures

4.1 Description of first aid measures:

Following inhalation: Pure wax resp. wax not containing any kind of oil is showing almost no vapour pressure when fluid, for that an inhalative absorbtion of any toxicologically concerned component can be excluded.

Following skin contact: Contact with molten/fluid product may lead to burns. Cool down with cold water immediately, if necessary treat wound in a sterile manner, seek for medical advice. Any absorption of paraffin components by means of skin while the wax is solid cannot be expected.

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Following eye contact: Rinse thoroughly with water, if necessary seek medical advice (when wax is hot/fluid)

Following ingestion: Rinse mouth – no further measures necessary.

Waxes can be applied as components of pharmaceuticals or food for this reason the question of absorption in the digestive tract after accidental ingestion is irrelevant.

4.2 Most important symptoms and effects, both acute and delayed Symptoms: none

Effects: none

4.3 Indication of any immediate medical attention and special treatment needed Notes for the doctor: none Special treatment: none

Section 5: Firefighting measures

- 5.1 Extinguishing media Suitable: Foam, dry powder, carbon dioxide, water mist spray Unsuitable: Water jet
- 5.2 Special hazards arising from the substance or mixture In case of fire fumes are possible: carbon monoxide (CO).

5.3 Advice for fire-fighters

Respiratory protection independent of ambient environment - in case of fumes.

5.4 Additional indication:

Fire class: B Liquid substances or substances becoming liquid.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures For non-emergency personnel

Protective equipment: Emergency procedures:

Avoid contact with skin, eyes and clothes when substance is hot and fluid.

For emergency responders

<u>Personal protective equipment:</u> see section 5.3 Avoid contact with skin, eyes and clothes when substance is hot and fluid.

6.2 Environmental precautions

No special precautions need to be taken.

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6.3 Methods and material for containment and cleaning up Let material solidify – clean up mechanically.

6.4 Reference to other sections

More information on disposal see section 13.

Section 7: Handling and storage

7.1 Precautions for safe handling

Fire preventions: No special precautions necessary. Regular preventive fire protection.

Aerosol and dust generation preventions: Avoid generation of dust – work under fume hood.

Environmental precautions: No special precautions necessary.

Advice on general occupational hygiene: Observe general hygiene rules.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Keep containers tightly closed and store cool, dry and well ventilated. Keep away from sun rays. Best at 5 – 30 $^\circ$ C.

Requirements for storage rooms and vesselsStore in original bundles. Room temperature see above.Storage class:11 (TRGS 510)Materials to avoid:n.a.

7.3 Specific end uses Sector specific guidelines: dental laboratories

Section 8: Exposure controls / personal protection

8.1 Control parameters

Occupational exposure limits

Substance: paraffin	; CAS-no. : 8002-74-2
Specification :	Does not contain any substances - according to the common EU lists – that have to be monitored at work-places.
Limit value type (country of origin) :	n.a.
Peak limitation:	n.a.
Toxic to reproduction:	n.a.
Source (TRGS)	n.a.

8.1.2 DNEL- and PNEC- values none

; CAS-Nr. :

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8.1.3 Control-Banding (e.g. ILO, EMKG)

8.2 Exposure controls The type and extent of usage determine the choice of protective measures.

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none

Appropriate engineering controls Provide good ventilation

Personal protective equipment

Eye / face protection

Safety glasses - not necessary if used according to the intended purpose.

Skin protection

Hand protection

in full contact: use appropriate safety gloves material: polychloroprene - CR (0,5 mm), nitrile rubber - NBR (0,35 mm) layer thickness (mm): see above penetration time (min.): 8 hours

Splash contact:use appropriate safety glovesmaterial:polychloroprene - CR (0,5 mm), nitrile rubber - NBR (0,35 mm)layer thickness (mm):see abovepenetration time (min.):8 hours

Body protection

Appropriate

Respiratory protection

Not required under normal use.

Thermal hazards

Physical state:

Not required under normal use.

Environmental exposure controls

Do not allow to get into sewer system, surface or ground water.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties:

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 Aggregate state: 	Solid, waxes in different shapes and colours
- colour :	various
Odour :	Characteristic, different according to type
Odour threshould :	No information available
pH-value:	n.a.
Freezing point :	< 50°C
Initial boiling point/boiling range :	n.a.
Flash point:	> 130°C
Evaporation rate :	n.a.
Flammability:	The substance is flammable, but does not intensify fires.
Upper/lower explosive limits	none
Vapour pressure :	n.a.

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Version: 3		Replaces Version: 2	
	Vapour density:	n.a.	
	Relative density:	ca. 0,93 g/cm ³	
	Solubility:	Not soluble in water	
	Partition coefficient:	n.a.	
	n-octanol/water:		
	Auto-ignition temperature:	n.a.	
	Decomposition temperature:	n.a.	
	Viscosity:	n.a.	
	explosive properties:	none	
	Oxidising properties:	none	
	Other information		
9.2	Ν	lo further information available	
	Physical hazards Explosives		

Section 10: Stability and reactivity

10.1 Reactivity: no known unusual reactivity

10.2Chemical stability: stable under regular conditions.

10.3 Possibility of hazardous reactions: no known hazardous reactions

10.4 Conditions to avoid: not designated

10.5 Incompatible materials: not designated

10.6 Hazardous decomposition products: carbon monoxide, carbon dioxide

Section 11: Toxicological information

11.1 Information on toxicological effects

When used appropriately no dangers to health are currently known Acute toxicity No information available on systemic effects. Skin irritation Danger of burns when handling hot and liquid waxes. Eye irritation May harm when working with hot and liquid waxes. Sensitisation to the respiratory tract / skin Vapors have a very weak irritant effect. Germ cell mutagenicity No information available

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Carcinogenicity

An extensive programme already realized in 1958 for clarifying the absence of carcinogical properties in pure waxes was followed by the admission as food ingredient. Reproductive toxicity No information available Specific target organ toxicity (single exposure) none

Specific target organ toxicity (repeated exposure) none

Aspiration hazard

No information available

Symptoms related to the physical, chemical and toxicological characteristics:

In case of ingestion:may have a laxative effectIn case of skin contact:may cause burns when wax hot and liquidIn case of inhalation:seems impossibleIn case of eye contact:seek for medical advice when eye contact with hot and liquid wax

Section 12: Ecological information

12.1 Toxicity

No information available

12.2 Persistence and degradability

No data available. As to consistency and non-solubility a bioavailability is very unlikely.

12.3 Bioaccumulative potential

Not significantly accumulative in living organisms.

12.4 Mobility in soil

No data available.

12.5 Results of PBT- and vPvB assessment

Not applicable.

12.60ther adverse effects

None

Section 13: Disposal considerations

13.1 Waste treatment methods

Contaminated packaging disposal Recycle acccording to official regulations.

Waste codes / waste designations according to EWC / AVV: No waste codes applicable.

Special precautions

Other relevant provisions for waste treatment national or EC

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Dispose of waste according to applicable legislation

Section 14: Transport information

14.1UN-no.

Not applicable

14.2UN proper shipping name

ADR/RID

The product is not defined under ADR/RID regulations.

IMDG-Code / ICAO-TI / IATA-DGR

The product is not defined under IMDG regulations.

14.3 Transport hazard class(es) / hazard labels

Not relevant

14.4 Packing group

Not relevant

14.5 Environmental hazards

Environmentally hazardous substance marking ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: yes / XXX no Marine Pollutant: yes / XXX no

14.6 Special precautions for user

No additional information available.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Pollution category (X, Y or Z) : not applicable Type of ship (1, 2 or 3) : not applicable

Section 15: Regulatory information

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

EU-regulations, e.g.:

Directive /EC) no. 2037/2000 (substances that deplete the ozone layer): not listed

Directive (EC) no. 850/2004 (persistent organic pollutants): not listed

Directive (EC) no. 689/2008 (Import and export of dangerous chemicals): not listed

Directive (EC) no. 648/2004 (Detergents Regulation): not listed

National regulations, e.g.:

Water hazard class (VwVwS) : not water pollutant / registration no. 268

Technical instructions on Air Quality Control (TA-Luft): not applicable

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Other relevant regulations: TRGS 500, 510 (Germany): storage class: 11 (flammable solids)

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out.

Section 16: Other information

Indication of changes

Regulation (EC) no. 1272/2008 (CLP, EU_GHS) Section1: Emergency number, editorial revision

Abbreviations and acronyms

n.a. Not applicable

Key literature references and sources for data

Gestis Stoffdatenbank - <u>http://gestis.itrust.de/</u> Authority for chemicals www.baua.de

Classification for mixtures and used evaluation method according to regulation (EC) 1207/2008 [CLP]:

No classification

Relevant R-, H- and EUH-phrases (number and full text):

None of the above stated phrases is relevant. P-phrases stated in section 2.2

Training advice

Not applicable for qualified dental technicians.

Further information

none

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