EU – Safety Data Sheet according to Regulation (EC) No 1907/2006



Page 1 of 6 Printing date: 10.01.2023 Replaces Version: 4

Date of issue: 23.04.2015 Valid from: 01.01.2015 Date of revision: 22.12.2022 Version: 5 **Dental waxes**

SEC	SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1	Product identifier Tradename:	All dental waxes 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	
1.2	Relevant identified uses of the substance or mixture and uses advised against Relevant identified uses:	to be used in dental labs exclusively	
1.3	Details of the supplier of the safety data sheet Manufacturer/Supplier: Street / mailbox: Country code. / postal code / city: Phone: Fax: E-mail / Website: Further information obtainable from:	al dente Dentalprodukte GmbH Borsigstr. 1 D - 38644 Goslar 0 53 21 / 80031 0 53 21 / 50881 <u>info@aldente.de</u> / <u>www.aldente.de</u> al dente Dentalprodukte GmbH	
1.4	Emergency telephone number al dente Dentalprodukte GmbH:	+49 (0) 53 21 / 80031 (Mo-Fr 8:00-16:00)	
SEC	TION 2: Hazards identification		
2.1	Classification of the substance or mixture Regulation (EC) No. 1272/2008:	This mixture is not classified as hazardous in accordance with Regulation (EC) No. 1272/2008.	
2.2	Label elements		
2.3	Other hazards:	No information available.	
SEC	TION 3: Composition/information on ingredie	nts	
3.2	Mixtures Chemical characterization:	Wax	
	Further Information:	No information available.	
SEC	TION 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 absorption 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.	
	Following eye contact:	Rinse thoroughly with water, if necessary seek medical advice (when wax is hot/fluid)	

		/ 6000 / 6000 / 6000 / 6000 / 600 / 600	
EU – Safety Data Sheet according to Regulation (EC) No 1907/2006 Date of issue: 23.04.2015 Valid from: 01.01.2015 Date of revision: 22.12.2022 Version: 5 Dental waxes		al dente dentalprodukte	
		Page 2 of 6 Printing date: 10.01.2023 Replaces Version: 4	
	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:	None.	
4.3	Indication of any immediate medical attention and special treatment needed:	None.	
SEC	TION 5: Firefighting measures		
5.1	Extinguishing media Suitable:	Foam, dry powder, carbon dioxide (CO2), water spray jet.	
	Unsuitable:	Full 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 environme – in case of fumes.	
5.4	Additional indication: Fire class: B:	Liquid substances or substances becoming liquid.	
	TION 6: Accidental release measures		
6.1	Personal precautions, protective equipment and emergency procedures:	Use personal protection equipment.	
6.2	Environmental precautions:	Do not allow to enter into surface water or drains.	
6.3	Methods and material for containment and cleaning up:	Take up mechanically. Avoid dust formation. Collect in closed and suitable containers for disposal.	
6.4	Reference to other sections:	See protective measures under point 7 and 8. Disposal: s section 13	
SEC	TION 7: Handling and storage		
7.1	Precautions for safe handling Advice on safe handling:	See section 8.	
	Advice on protection against fire and explosion:	No special fire protection measures are necessary.	
	Further information on handling:		
7.2	Conditions for safe storage, including any i Requirements for storage rooms and vessels:	i ncompatibilities Store in a cool dry place. Keep/Store only in original container. Protect against direc sunlight.	
	Hints on joint storage:	No special measures are necessary.	
7.3	Specific end uses:	No further relevant information available.	

EU – Safety Data Sheet

according to Regulation (EC) No 1907/2006

Page 3 of 6 Printing date: 10.01.2023 Replaces Version: 4

Date of issue: 23.04.2015 Valid from: 01.01.2015 Date of revision: 22.12.2022 Version: 5 **Dental waxes**

SECTION 8: Exposure controls/personal protection Control parameters 8.1 **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. DNEL- and PNEC- values: None. Control-Banding (e.g. ILO, EMKG): None. 8.2 **Exposure controls:** Technical ventilation of workplace Appropriate engineering controls: Provide good ventilation. Protective and hygiene measures: Work in well-ventilated zones or use proper respiratory protection. Only wear fitting, comfortable and clean protective clothing. Wash hands before breaks and after work. Separate storage of work clothes. Eye/face protection: Suitable eye protection: Eye glasses with side protection goggles Hand protection: No special measures are necessary. Skin protection: Protective clothing. **Respiratory protection:** Particle filter device (DIN EN 143) **SECTION 9: Physical and chemical properties**

9.1	.1 Information on basic physical and chemical properties:	
	Physical state:	Solid, waxes in different shapes and colours
	Colour:	various
	Odour:	Characteristic, different according to type
	pH-value:	Not available
	Freezing point :	< 50°C
	Melting point:	not determined
	Initial boiling point/boiling range :	not applicable
	Sublimation point:	not determined
	Pour point:	not determined
	Flash point:	> 130°C
	Evaporation rate:	not applicable
	Flammability:	The substance is flammable, but does not intensify fires.
	Upper/lower explosive limits	none
	Vapour pressure:	not applicable
	Vapour density:	not applicable
	Relative density:	ca. 0,93 g/cm³
	Solubility:	Not soluble in water
	Partition coefficient n-octanol/water:	not applicable
	Auto-ignition temperature:	not determined
	Decomposition temperature:	not determined

Date of issue: 23.04.2015 Valid from: 01.01.2015 Date of revision: 22.12.2022

Dental waxes

Version: 5



Page 4 of 6 Printing date: 10.01.2023 Replaces Version: 4

	Viscosity:	not applicable
	Explosive properties:	none
	Oxidising properties:	none
9.2	Other information:	No further information available.
SEC	TION 10: Stability and reactivity	
10.1	Reactivity:	No known unusual reactivity.
10.2	Chemical stability:	Stable under regular conditions.
10.3	Possibility of hazardous reactions:	No known hazardous reactions.
10.4	Conditions to avoid:	Heat dissipation.
10.5	Incompatible materials:	Not designated.
10.6	Hazardous decomposition products:	Carbon monoxide, carbon dioxide.
SEC	TION 11: Toxicological information	
11.1	Information on toxicological effects	When used appropriately no dangers to health are currentl known
	Acute toxicity:	No information available on systemic effects.
	Skin irritation:	Based on available data, the classification criteria are not met.
	Eye irritation:	Based on available data, the classification criteria are not met.
	Sensitisation to the respiratory tract:	Vapours have a very weak irritant effect.
	Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
	Carcinogenicity:	An extensive programme already realized in 1958 for clarifying the absence of carcinogenic properties in pure waxes was followed by the admission as food ingredient.
	Reproductive toxicity:	Based on available data, the classification criteria are not met.
	Specific target organ toxicity (single exposure):	Based on available data, the classification criteria are not met.
	Specific target organ toxicity (repeated exposure):	Based on available data, the classification criteria are not met.
	Aspiration hazard:	Not applicable
SEC.	TION 12: Ecological information	
12.1	Toxicity:	No information available

		- fanne i ann i ann i ann i ann i ann i an
EU – Safety Data Sheet according to Regulation (EC) No 1907/2006		al dente dentalprodukte
Date of issue: 23.04.2015		Page 5 of 6
	from: 01.01.2015 of revision: 22.12.2022 Version: 5	Printing date: 10.01.2023 Replaces Version: 4
Date of revision. 22. 12.2022 Version. 5		Replaces version. 4
		,
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 information available
12.5	Results of PBT- and vPvB assessment:	The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.
12.6	Other adverse effects:	Not hazardous to water - no further quantitative data on ecotoxic effects are available.
SEC	TION 13: Disposal considerations	
13.1	Waste treatment methods:	Contaminated packaging disposal Recycle according to official regulations.
	Waste codes / waste designations according to EWC / AVV:	No waste codes applicable.
	Special precautions:	None.
	Other relevant provisions for waste treatment national or EC:	Dispose of waste according to applicable legislation.
SEC	FION 14: Transport information	
14.1	UN-no.:	No dangerous good in sense of this transport regulation.
14.2	UN proper shipping name	
	ADR/RID:	No dangerous good in sense of this transport regulation.
		No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation.
14.3	ADR/RID: IMDG-Code / ICAO-TI / IATA-DGR:	No dangerous good in sense of this transport regulation.
14.3 14.4	ADR/RID: IMDG-Code / ICAO-TI / IATA-DGR: Transport hazard class(es) / hazard labels:	No dangerous good in sense of this transport regulation.
	ADR/RID: IMDG-Code / ICAO-TI / IATA-DGR: Transport hazard class(es) / hazard labels: Packing group:	No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation.
14.4	ADR/RID: IMDG-Code / ICAO-TI / IATA-DGR: Transport hazard class(es) / hazard labels: Packing group:	No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation.
14.4 14.5	ADR/RID: IMDG-Code / ICAO-TI / IATA-DGR: Transport hazard class(es) / hazard labels: Packing group: Environmental hazards	No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation.
14.4 14.5 14.6	ADR/RID: IMDG-Code / ICAO-TI / IATA-DGR: Transport hazard class(es) / hazard labels: Packing group: Environmental hazards Marine Pollutant:	No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. No
14.4 14.5 14.6 14.7	ADR/RID: IMDG-Code / ICAO-TI / IATA-DGR: Transport hazard class(es) / hazard labels: Packing group: Environmental hazards Marine Pollutant: Special precautions for user: Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. No No dangerous good in sense of this transport regulation.
14.4 14.5 14.6 14.7	ADR/RID: IMDG-Code / ICAO-TI / IATA-DGR: Transport hazard class(es) / hazard labels: Packing group: Environmental hazards Marine Pollutant: Special precautions for user: Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. No No dangerous good in sense of this transport regulation.
14.4 14.5 14.6 14.7 <u>SEC</u>	ADR/RID: IMDG-Code / ICAO-TI / IATA-DGR: Transport hazard class(es) / hazard labels: Packing group: Environmental hazards Marine Pollutant: Special precautions for user: Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code <u>TION 15: Regulatory information</u> Safety, health and environmental regulation EU-regulations, e.g.:	No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. No No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation.
14.4 14.5 14.6 14.7 <u>SEC</u>	ADR/RID: IMDG-Code / ICAO-TI / IATA-DGR: Transport hazard class(es) / hazard labels: Packing group: Environmental hazards Marine Pollutant: Special precautions for user: Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code <u>TION 15: Regulatory information</u> Safety, health and environmental regulatior	No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. No No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation.

EU – Safety Data Sheet

according to Regulation (EC) No 1907/2006

al dente dentalprodukte

Page 6 of 6 Printing date: 10.01.2023 Replaces Version: 4

Date of issue: 23.04.2015 Valid from: 01.01.2015 Date of revision: 22.12.2022 Version: 5 Dental waxes

15.2 Chemical safety assessment:

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Abbreviations and acronyms		
ADR:	Accord européen sur le transport des marchandises dangereuses par Route (European	
	Agreement concerning the International Carriage of Dangerous Goods by Road)	
RID:	Règlement international conernat le transport des marchandises dangereuses par chemin	
	de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)	
IMDG:	International Maritime Code for Dangerous Goods	
IATA:	International Air Transport Association	
IATA-DGR:	Dangerous Goods Refulations by the "International Air Transport Association"	
(IATA) ICAO:	International Civil Aviation Organization	
ICAO-TI:	Technical Instructions by the "International Civil Aviation Organization" (ICAO)	
CAS:	Chemical Abstracts Service (division of the American Chemical Society)	
GHS:	Globally Harmonized System of Classification and Labelling of Chemicals	
CLP:	Regulation on Classification, Labelling and Packaging of Substances and Mixtures	
LC50:	Lethal concentration, 50 percent	
LD50:	Lethal dose, 50 percent	
EC50:	Effectice concentration, 50 percent	
DNEL:	Derived No Effect Level	
PNEC:	Predicted No Effect Concentration	
PBT:	Persistent, Bioaccumulative and Toxic	
vPvB:	very Persistent and very Bioaccumulative	

Further information:

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)