

according to Regulation (EC) No. 1907/2006 (REACH), Article 31  
Revision date: 24.05.2018 Version number 4

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**ISO-PRO 3D****SECTION 1: Identification of the substance / mixture and Company**

- 1.1 Product identifier**  
Commercial product name: ISO-PRO 3D
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**  
Application of the substance / the mixture: Separating agent for Polyether/Polyurethane and Silicone/Silicone materials
- 1.3 Details of the supplier of the safety data sheet**  
**Company / Manufacturer:** 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](mailto:info@aldente.de) / [www.aldente.de](http://www.aldente.de)  
Further information obtainable from: 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**



GHS02 flame  
Flam. Liq. 2

H225 Highly flammable liquid and vapour.



GHS08 health hazard  
Asp. Tox. 1

H304 May be fatal if swallowed and enters airways.



GHS09 environment  
Aquatic Chronic 2

H411 Toxic to aquatic life with long lasting effects.



GHS07  
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.

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**Hazard pictograms**



GHS02 GHS07 GHS08 GHS09

**Signal word:** Danger

**Hazard-determining components of labelling:** Hydrocarbons, C7-C9, n-Alkane, Isoalkane, Cyclene

**Hazard statements**

H225 Highly flammable liquid and vapour.  
H336 May cause drowsiness or dizziness.  
H304 May be fatal if swallowed and enters airways.  
H411 Toxic to aquatic life with long lasting effects.

**Precautionary statements**

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.  
P331 Do NOT induce vomiting.  
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.  
P405 Store locked up.  
P501 Dispose of contents/container in accordance with local/regional/national/ international regulations.

**Additional information:**

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**

**3.2 Chemical characterization:** Mixture.  
**Description:** Dispersion of wax in a solvent mixture.

Dangerous components:		
EC number: 920-750-0	Hydrocarbons, C7-C9, n-Alkane, Isoalkane, Cyclene	50-100%
	 Flam. Liq. 2, H225; Asp. Tox. 1, H304; Aquatic Chronic 2, H411;  STOT SE 3, H336	

**SVHC:** Not applicable  
**Additional information:** For the wording of the listed hazard phrases refer to section 16.

**SECTION 4: First aid measures**

**4.1 After inhalation:**  
**General information:** Immediately remove any clothing soiled by the product.  
**After inhalation:** Supply fresh air; consult doctor in case of complaints.

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<b>After skin contact:</b>	Immediately wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.
<b>After eye contact:</b>	Rinse opened eye for several minutes under running water. Then consult a doctor.
<b>After swallowing:</b>	Rinse out mouth and then drink plenty of water. If swallowed or in case of vomiting, danger of entering the lungs. Do not induce vomiting. Call a doctor immediately.
<b>4.2 Most important symptoms and effects, both acute and delayed:</b>	Headache Dizziness Vomitus Tiredness
<b>4.3 Indication of any immediate medical attention and special treatment needed</b>	No further relevant information available.

**SECTION 5: Fire Fighting measures:**

<b>5.1 Extinguishing media</b>	
<b>Suitable extinguishing media:</b>	CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
<b>For safety reasons unsuitable extinguishing agents:</b>	Water with full jet
<b>5.2 Special hazards arising from the substance or mixture:</b>	In case of fire, the following can be released: Carbon monoxide and carbon dioxide
<b>5.3 Advice for firefighters</b>	
<b>Protective equipment:</b>	Wear self-contained respiratory protective device.

**SECTION 6: Accidental release measures**

<b>6.1 Personal precautions, protective equipment and emergency procedures:</b>	Do not breathe vapour/spray. Keep away from ignition sources. Wear protective equipment. Keep unprotected persons away. Avoid contact with skin and eyes.
<b>6.2 Environmental precautions:</b>	Prevent seepage into sewage system, work pits and cellars. Inform respective authorities in case of seepage into watercourse or sewage system. Do not allow to enter sewers/ surface or ground water.
<b>6.3 Methods and material for containment and cleaning up:</b>	Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose contaminated material as waste according to item 13. Ensure adequate ventilation.
<b>6.4 Reference to other sections:</b>	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.


**SECTION 7: Handling and Storage**

<b>7.1 Precautions for safe handling:</b>	Prevent formation of aerosols. Avoid contact with skin and eyes. Ensure good ventilation/exhaustion at the workplace.
<b>Information about fire - and explosion protection:</b>	Traces of flammable substances may collect in the steam chamber of enclosed systems. Keep clear of ignition sources. Keep ignition sources away - Do not smoke. Protect against electrostatic charges.
<b>7.2 Conditions for safe storage, including any incompatibilities</b>	
<b>Storage:</b>	
<b>Requirements to be met by storerooms and receptacles:</b>	Protect from heat and direct sunlight. Store between 15°C and 30°C. Store at a well ventilated place. Store in a cool location.
<b>Information about storage in one common storage facility:</b>	Not required.
<b>Further information about storage conditions:</b>	Store in cool, dry conditions in well-sealed receptacles.
<b>7.3 Specific end use(s):</b>	No further relevant information available.

**SECTION 8: Exposure controls / Personal protection**

<b>Additional information on the design of technical systems:</b>	No further information, see Section 7.
<b>8.1 Ingredients with limit values that require monitoring at the workplace:</b>	The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
<b>DNELs:</b>	Hydrocarbons C7-C9, n-Alkane, Isoalkane, Cyclene
Worker, DNEL, long-term:	dermal, systemic, 773 mg/kg KG/d inhalation, systemic, 2035 mg/m <sup>3</sup>
User, DNEL, long-term:	dermal, systemic, 699 mg/kg KG/d inhalation, systemic, 608 mg/m <sup>3</sup>
<b>Additional information:</b>	The lists valid during the making were used as basis.
<b>8.2 Exposure controls</b>	
<b>Personal protective equipment:</b>	
<b>General protective and hygienic measures:</b>	General protective and hygienic measures: Keep away from foodstuffs, beverages and feed. Do not eat or drink while working. Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin. Do not inhale gases / fumes / aerosols.

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<b>Respiratory protection:</b>	Use suitable respiratory protective device in case of insufficient ventilation. Short term filter device: Particle filtering halfmask, Filtering face piece FFP3 (Mask P3)
<b>Protection of hands:</b>	Protective gloves should be changed regularly, especially after intensive contact with the product. For every workplace a suitable type of protective gloves must be selected. The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
<b>Material of gloves:</b>	Butyl rubber ( 0,7 mm) EN 374 As there are many different conditions in every day work these indications can only serve as an aid to orientation for the selection of suitable gloves for the handling of chemical products. By no means they can replace qualifying examinations by the end-user. These recommendations only apply to the product mentioned in the safety data sheet. When mixing with other substances or under conditions deviant from norm EN 374 a manufacturer of CE-approved gloves should be referred to. 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 cannot be calculated in advance and has therefore to be checked prior to the application.
<b>Penetration time of glove material:</b>	The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed. The determined penetration times according to EN 374 part III are not performed under practical conditions. Therefore a maximum wearing time, which corresponds to 50% of the penetration time, is recommended.
<b>Eye protection:</b>	 Tightly sealed goggles
<b>Body protection:</b>	Protective work clothing

**SECTION 9. Physical and chemical properties**

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

**General information:**

**Appearance:**

<b>Form:</b>	Fluid
<b>Colour:</b>	Colourless
<b>Odour:</b>	Characteristic
<b>Odour threshold:</b>	Not determined.
<b>pH-value:</b>	Not determined.

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<b>Change in condition:</b>	
<b>Melting point/freezing point:</b>	Undetermined.
<b>Initial boiling point and boiling range:</b>	>95 °C
<b>Flash point:</b>	<10 °C
<b>Flammability (solid, gaseous):</b>	Not applicable.
<b>Ignition temperature:</b>	>200 °C
<b>Decomposition temperature:</b>	Not determined.
<b>Self-igniting:</b>	Product is not self-igniting.
<b>Danger of explosion:</b>	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
<b>Explosion limits:</b>	
<b>Lower:</b>	0.7 Vol %
<b>Upper:</b>	7.7 Vol %
<b>Oxidising properties:</b>	Not determined
<b>Vapour pressure:</b>	Not determined
<b>Density at 20°C:</b>	0.77 g/cm <sup>3</sup> (DIN 51757)
<b>Relative density:</b>	Not determined.
<b>Vapour density:</b>	Not determined.
<b>Evaporation rate:</b>	Not determined.
<b>Solubility in / miscibility with water:</b>	Not miscible or difficult to mix.
<b>Partition coefficient (n-octanol/water):</b>	Not determined.
<b>Viscosity:</b>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic at 40 °C:</b>	<20 mm <sup>2</sup> /s (3 EN ISO 2431)
<b>Solvent content:</b>	
<b>Solids content:</b>	0.0 %

**9.2 Other information:** No further relevant information available.

**SECTION 10: Stability and Reactivity**

<b>10.1 Reactivity</b>	No dangerous reactions if used according to specifications.
<b>10.2 Chemical stability:</b>	Stable if used according to specifications
<b>Thermal decomposition / conditions to be avoided:</b>	Protect from heat and direct sunlight. No decomposition if used according to specifications.
<b>10.3 Possibility of hazardous reactions:</b>	Forms explosive gas mixture with air. Reacts with strong oxidising agents.
<b>10.4 Conditions to avoid:</b>	No further relevant information available.
<b>10.5 Incompatible materials:</b>	No further relevant information available.
<b>10.6 Hazardous decomposition products:</b>	Formation of following substances is possible in case of fire: Carbon monoxide and carbon dioxide

**Section 11: Toxicological Information**

<b>11.1 Information on toxicological effects</b>	
<b>Acute toxicity:</b>	Based on available data, the classification criteria are not met.

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<b>LD/LC50 values relevant for classification:</b>		
<b>Hydrocarbons, C7-C9, n-Alkane, Isoalkane, Cyclene</b>		
Oral	LD50	5,840 mg/kg (rat) (OECD 401)
Dermal	LD50	2,920 mg/kg (rat) (OECD 402)
Inhalative	LC50/4 h	23.3 mg/l (rat) (OECD 403)

**Primary irritant effect:**

**Skin corrosion/irritation:** Based on available data, the classification criteria are not met.

**Serious eye damage/irritation:** Based on available data, the classification criteria are not met.

**Respiratory or skin sensitisation:** Based on available data, the classification criteria are not met.

**Additional toxicological information:** Degrease of skin caused by repeated skin contact.

**CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)** Note P  
 This product contains < 0.1% benzene.  
 The classification as carcinogen or mutagen is not required.

**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.

**STOT-single exposure** May cause drowsiness or dizziness.

**STOT-repeated exposure:** Based on available data, the classification criteria are not met.

**Aspiration hazard:** May be fatal if swallowed and enters airways.

**SECTION 12: Ecological Information**

**12.1 Toxicity**

**Aquatic toxicity:** The product is swimming on water and evaporates easily from water surface.

**12.2 Persistence and degradability:** No further relevant information available.

**12.3 Bioaccumulative potential:** No further relevant information available.

**12.4 Mobility in soil:** No further relevant information available.

**Ecotoxicological effects:**  
**Remark:** Toxic for fish

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**Additional ecological information:**

**General notes:**

Do not allow product to reach ground water, water course or sewage system. Danger to drinking water if even small quantities leak into the ground.  
Also poisonous for fish and plankton in water bodies.  
Toxic for aquatic organisms

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

**PBT:**

Not applicable.

**vPvB:**

Not applicable.

**12.6 Other adverse effects:**

No further relevant information available.

**SECTION 13: Disposal Considerations**

**13.1 Waste treatment methods:**

Must not be disposed together with household garbage.  
Do not allow product to reach sewage system.  
Disposal must be made according to official regulations.

**Waste disposal key:**

120107

**European waste catalogue:**

16 00 00 WASTES NOT OTHERWISE SPECIFIED IN THE LIST  
16 03 00 off-specification batches and unused products  
16 03 05\* organic wastes containing hazardous substances  
HP 3 Flammable  
HP 5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity  
HP 14 Ecotoxic

**Uncleaned packaging – Recommendation:**

Disposal must be made according to official regulations.

**SECTION 14: Transport Information**

**14.1 UN-Number**

**ADR, IMDG, IATA:**

UN3295

**14.2 UN proper shipping name**

**ADR:**

3295 KOHLENWASSERSTOFFE, FLÜSSIG, N.A.G.  
(Dampfdruck bei 50°C höchstens 110 kPa),

**IMDG:**

UMWELTGEFÄHRDEND  
HYDROCARBONS, LIQUID, N.O.S., MARINE  
POLLUTANT

**IATA:**

HYDROCARBONS, LIQUID, N.O.S.

**14.3 Transport hazard class:**

**ADR, IMDG**



**Class:**

3 Flammable liquids.

**Label:**

3

**IATA**



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**Class:** 3 Flammable liquids.  
**Label:** 3

**14.4 Packaging group:**  
**ADR, IMDG, IATA:** II

**14.5 Environmental hazards:**  
**Marine pollutant:** Yes  
 Symbol (fish and tree)  
**Special marking (ADR):** Symbol (fish and tree)

**14.6 Special precautions for user:** Warning: Flammable liquids.  
**Danger code (Kemler):** 33  
**EMS number:** F-E,S-D  
**Stowage Category:** B

**14.7 Transport in bulk according to Annex II of the MARPOL Agreement and according to the IBC Code:** Not applicable.

**Transport/Additional information:**  
**ADR**

**Limited quantity (LQ):** 1L  
**Excepted quantities (EQ):** Code: E2  
 Maximum net quantity per inner packaging: 30 ml  
 Maximum net quantity per outer packaging: 500 ml

**Transport category:** 2  
**Tunnel restriction code:** D/E  
**IMDG**  
**Limited quantities (LQ):** 1L  
**Excepted quantities (EQ):** Code: E2  
 Maximum net quantity per inner packaging: 30 ml  
 Maximum net quantity per outer packaging: 500 ml

**UN "Model Regulation":** UN 3295 HYDROCARBONS, LIQUID, N.O.S. (VAPOUR PRESSURE AT 50°C NOT MORE THAN 110 KPA), 3, II, ENVIRONMENTALLY HAZARDOUS

**SECTION 15: Regulatory Information**

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

**Directive 2012/18/EU**  
**Named dangerous substances - ANNEX I:** None of the ingredients is listed.  
**Seveso category:** E2 Hazardous to the Aquatic Environment  
 P5c FLAMMABLE LIQUIDS

**Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t  
**Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t

**REGULATION (EC) No 1907/2006 ANNEX XVII:** Conditions of restriction: 3, 40

**ISO-PRO 3D****15.2 Chemical safety assessment:**

A Chemical Safety Assessment has not been carried out.

**SECTION 16: Further Information**

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The information is based on the current state of our knowledge, however, it does not represent a guarantee of product characteristics and does not establish a contractual legal relationship.

**Relevant sentences:**

H225	Highly flammable liquid and vapour.
H304	May be fatal if swallowed and enters airways.
H336	May cause drowsiness or dizziness.
H411	Toxic to aquatic life with long lasting effects.

**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
ADR:	Accord européen sur le transport 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)
LC50:	Lethal concentration, 50 percent
LD50:	Lethal dose, 50 percent
PBT:	Persistent, Bioaccumulative and Toxic
SVHC:	Substances of Very High Concern
vPvB:	very Persistent and very Bioaccumulative
Flam. Liq. 2:	Flammable liquids – Category 2
STOT SE 3:	Specific target organ toxicity (single exposure) – Category 3
Asp. Tox. 1:	Aspiration hazard – Category 1
Aquatic Chronic 2:	Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

\* Data changed versus the previous version