

According to 1907/2006/EC, Article 31
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Gingiva Iso Spray

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

1.1 Product Identifier

Commercial product name: Gingiva Iso Spray

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

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
Further information obtainable from: al dente Dentalprodukte GmbH

1.4 Emergency telephone number

al dente Dentalprodukte GmbH: +49 (0) 53 21 / 80031 (Mon-Fri. 8 a.m. – 4 p.m.)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture:

Classification according to Regulation (EC) No 1272/2008:

Flam. Gas. 1, H220	Extremely flammable gas
Press. Gas, H280	Contains gas under pressure; may explode if heated
Repr. 2; H361f;	Suspected of damaging fertility or the unborn child
STOT RE 2; H373	May cause damage to organs through prolonged or repeated exposure.
Asp. 1; H304	May be fatal if swallowed and enter airways
Skin Irrit. 2, H315	Causes skin irritation
STOT SE 3; H336	May cause drowsiness or dizziness
Aquatic Chronic 2, H411	Toxic to aquatic life with long lasting effects

Information concerning particular hazards for human and environment:

The product has to be labelled due to calculation procedure for the "General Classification guideline for preparations of the EU" in the latest version.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008:

Hazard pictograms:



Signal word

Danger

Hazard statements

H220	Extremely flammable gas
H280	Contains gas under pressure; may explode if heated
H361f	Suspected of damaging fertility or the unborn child
H373	May cause damage to organs through prolonged or repeated exposure.
H304	May be fatal if swallowed and enter airways
H315	Causes skin irritation
H336	May cause drowsiness or dizziness
H411	Toxic to aquatic life with long lasting effects

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Precautionary statements

P210	Keep away from heat/sparks/open flames/hot surfaces. – No smoking.
P301 + P310	IF SWALLOWED: immediately call a POISON CENTER or doctor/physician
P331	Do NOT induce vomiting
P410 + P403	Protect from sunlight and store in a well-ventilated place.
P260	Do not breathe dust/fume/gas/mist/vapours/spray
P281	Use personal protective equipment as required
P271	Use only outdoors or in well ventilated areas

Reduced labelling (≤ 125 ml)

Hazard pictograms



Signal word

Danger

Hazard statements

H220	Extremely flammable gas
H280	Contains gas under pressure; may explode if heated
H304	May be fatal if swallowed and enter airways
H361f	Suspected of damaging fertility or the unborn child

Precautionary statements

P210	Keep away from heat/sparks/open flames/hot surfaces. – No smoking.
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P301 + P310	IF SWALLOWED: immediately call a POISON CENTER or doctor/physician
P331	Do NOT induce vomiting

2.3 Other hazards

Results of PBT and vPvB assessment

PBT:	not applicable
vPvB:	not applicable

SECTION 3: Composition/information on ingredients

3.1 Chemical characterization: Mixture

Description: Solution of paraffines in hexane

Hazardous components:

CAS 110-54-3; EINECS 203-777-6	n-hexane	GHS02, GHS07, GHS08, GHS09 H225, H361f, H304, H373, H315, H3396, H411
CAS 75-28-5; EINECS 200-857-2	isobutane	GHS02, H224
CAS 74-98-6; EINECS 200-827-9	propane	GHS02, H224
CAS 106-97-8; EINECS 203-448-7	butane	GHS02, H220, H280
CAS 78-78-4; EINECS 201-142-8	2-methylbutane	GHS02, GHS08, GHS09, H224, H304, H411, H336

SECTION 4: First aid measures

4.1 General information:	Seek medical advice, if symptoms occur, which can be caused by the product.
After skin contact:	Wash off with plenty of water and soap and rinse thoroughly.
After inhalation:	Fresh air. Consult a physician.

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After eye contact:	Rinse opened eye for several minutes under running water and consult an ophthalmologist.
After swallowing:	Rinse out mouth and then drink plenty of water. Caution if victim vomits. Risk of aspiration! Keep airways free. Call a physician immediately.

SECTION 5: Firefighting measures

5.1 Extinguishing media:	CO2, powder, sand. Vapours are heavier than air. Development of hazardous combustion gases and vapours possible in the event of fire.
5.2 Special hazards arising from the substance or mixture::	May form explosive gas-air mixtures.
5.3 Protective equipment	Wear self-contained respiratory protective equipment.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:	Do not inhale vapours/aerosols. Avoid substance contact. Ensure supply of fresh air in enclosed rooms. Keep away from ignition sources.
6.2 Environmental precautions:	Do not allow to enter drains/surface water/ ground-water.
6.3 Methods for cleaning up:	Absorb with liquid binding material. Forward for disposal. Clean up affected area.
6.4 Reference to other sections:	See Section 7 for information on safe handling See Section 8 for information on personal protection equipment See Section 13 for disposal information

SECTION 7: Handling and storage

7.1 Handling:	This product should only be supplied or handled to dentists or dental technicians or upon their instructions.
Precautions for safe handling:	Observe normal care for working with chemicals. Keep containers closed. Use only in well-ventilated areas. Do not inhale substance. Keep away from heat and direct sunlight.
Information about fire and explosion protection:	Keep away from heat and ignition sources, do not smoke. Do not spray on flames or red-hot objects. Beware: Container is pressurized. Keep away from direct sun exposure and temperatures over 50°C. Do not open by force or throw into fire even after use.
7.2 Storage:	Store at a cool and dry place. Store tightly closed. Storage temperature 15-25°C (60-80°F).
Requirements at storerooms and containers:	Store only in the original containers
Further information on storage conditions:	Store away from food stuffs. Heat will increase pressure and may lead to the container exploding. Protect from heat and direct sunlight.

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7.3 Specific end uses: No further relevant information available

SECTION 8: Exposure controls/personal protection

8.1 Components with limits of values to be supervised at the workplace:

CAS-No.	name	art	value	unit
110-54-3	n-hexane	AGW (TRGS 900)	50 ml/m ³	180mg/m ³
75-28-5	isobutane	AGW (TRGS 900)	1000 ml/m ³	2400mg/m ³
74-98-6	propane	AGW (TRGS 900)	1000 ml/m ³	1800mg/m ³
106-97-8	butane	AGW (TRGS 900)	1000 ml/m ³	2400 mg/m ³
78-78-4	2-methylbutane	AGW (TRGS 900)	1000 ml/m ³	3000 mg/m ³

Additional information: The lists valid during the making were used as basis

8.2 Personal protective equipment: General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.
Keep away from foodstuffs and beverages. Do not inhale gases/fumes/aerosols.

Hand protection

Protective gloves.
Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection:

Safety glasses.

Respiratory protection:

Required, when vapours/aerosols are generated.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance

Form:	liquid
Colour:	colourless
Odour:	characteristic
	Value Unit Method

Safety relevant basic data

Melting point/melting range:	n.a
Boiling point/boiling range:	n.d.
Flash point:	ca. -80 °C
Ignition temperature:	Product is not self-igniting
Danger of explosion:	Product is not explosive. However, formation of explosive air/vapour mixtures is possible
Critical values for exposure:	lower: 1,5 Vol%, upper 10,9 Vol%
Density:	0.60 (20 °C) g/cm ³
Vapor pressure:	n.a.
pH:	neutral
Solubility in/miscibility with:	miscible with most organic solvents; alcohols
Water:	insoluble
Content of solvents:	
Organic solvents:	n-hexane

SECTION 10: Stability and reactivity

10.4 Thermal decomposition / conditions to be avoided

Possibility of hazardous reactions: no information available

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Conditions to avoid: Protect from heat and direct sunlight. Forms explosive gas mixture with air. Danger of containers bursting at temperatures >55°C because of high vapour pressure.

10.6 Hazardous decomposition products: No information available.

SECTION 11: Toxicological information**11.1 Acute toxicity: (n-hexane)**

n-hexane: LD50 (oral, rat): 16000 mg/kg
n-hexane: LC50 (inhalativ, rat): 172 mg/l; 4h; Dampf
2-methylbutane: LC50 (inhalativ, rat): 1280 mg/l; 4h;
butane: LC50 (inhalativ, rat): 658 mg/l; 4h;

Primary irritation:

skin: Irritating for skin and mucous membrane.
eye: Slight irritations possible.
Sensitization: No sensitizing effect known.

11.2 Additional toxicological information: If handled in accordance with good industrial hygiene and safety practice and according to specifications no health diseases are reported.

SECTION 12: Ecological information

12.1 General information: Do not allow to enter drains/canalization/ground-water

Classification of water endangerment: The product contains materials that are harmful for the environment. Toxic for aquatic organisms. WGK=2 (polluting substance).

SECTION 13: Disposal considerations

13.1 Product:
Recommendation: Disposal must be made according to official regulations

13.2 Uncleaned packaging: Packaging that cannot be cleaned are to be disposed of in the same manner as the product.

Recommendation: Disposal must be made according to official regulations

SECTION 14: Transport information

Land transport ADR/RID and GGVs/GGVE (Germany): UN 1950
AEROSOLS, flammable, 2.1

Sea transport IMDG: UN 1950
AEROSOLS, flammable, 2.1

Air transport ICAO-TI and IATA-DGR: UN 1950
AEROSOLS, flammable, 2.1

The transport regulations are cited according to international regulations and in the form applicable in Germany. Possible national deviations in other countries are not considered.

SECTION 15: Regulatory information

15.1 Classification according to EC-guidelines: The product has to be labelled according to EC-regulations or the corresponding national regulations.

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15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Changes compared with the previous version:

Adaptation according to 1907/2006/EG, Article 31

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to products properties.

However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.