

**Safety data sheet** in accordance with regulation (EC) no. 1907/2006  
(amended by regulation (EU) Nr. 453/2010)

Date of issue: 28.08.2018

Gingiva Mask Iso-Spray

Date of revision:

03-3350

Valid from: 28.12.20

Version: 2

Replaces version: 1

**1. Identification of the substance / Preparation and Company:**

Identification of the substance or preparation:

Commercial product name: Gingiva Mask Iso-Spray (Separating agent for silicones)

Company / Manufacturer:

al dente Dentalprodukte GmbH

Borsigstr. 1

D – 38644 Goslar

+49(0) 5321-80031

+49(0) 5321-50881

[info@aldente.de](mailto:info@aldente.de) / [www.aldente.de](http://www.aldente.de)

**2. Hazards identification**

2.1 Classification of the substance or mixture:

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

Flam. Liq. 1, H224 Extremely flammable liquid and vapour

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

H224

Extremely flammable liquid and vapour

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

Precautionary statements

P301 + P310

IF SWALLOWED: immediately call a POISON CENTER or doctor/physician

P331

Do NOT induce vomiting

P403

Store in a well-ventilated place.

P210

Keep away from heat/sparks/open flames/hot surfaces. – No smoking.

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

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Signal word

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Precautionary statements

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IF SWALLOWED: immediately call a POISON CENTER or doctor/physician

P331

Do NOT induce vomiting

Labelling according to EU guidelines:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical

contact with the human body; are exempted from the provisions of Regulation (EC) No. 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

2.3

Other hazards

Results of PBT and vPvB assessment

PBT: not applicable

vPvB: not applicable

### 3. Composition/Information on Ingredients

|     |                            |  |
|-----|----------------------------|--|
| 3.1 | Chemical characterization: | Mixture  |
|     | Description:               | Solution of paraffines in hexane   |
|     | Hazardous components:      |  |
|     | CAS 110-54-3; EG 203-777-6 | n-hexane GHS02, GHS07, GHS08, GHS09 H225, H361f, H304, H373, H315, H3396, H411 |
|     | CAS 75-28-5; EG 200-857-2  | isobutane GHS02, H224  |
|     | CAS 74-98-6; EG 200-827-9  | propane GHS02, H224  |

### 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.  |
|     | 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. |

### 5. Firefighting measures

|     |   |  |
|-----|---|--|
| 5.1 | Extinguishing media:                                  |  |
|     | CO <sub>2</sub> , powder, sand. Do not use water      |  |
| 5.2 | Special hazards arising from the substance or mixture | No further relevant information available            |
| 5.3 | Protective equipment                                  | Wear self-contained respiratory protective equipment |

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**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<br>See Section 8 for information on personal protection equipment<br>See Section 13 for disposal information |

**7. Handling and storage**

|     |  |  |
|-----|--|--|
| 7.1 | Handling:  | This product should only be supplied or handled to dentists or dental technicians or upon their instructions. 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. |
|     | Precautions for safe handling:                   | 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.                                |
|     | Information about fire and explosion protection: | Store at a cool and dry place. Store tightly closed. Storage temperature 15-25°C (60-80°F).  |
| 7.2 | Storage:   | Store only in the original containers<br>Store away from food stuffs.<br>Heat will increase pressure and may lead to the container exploding. Protect from heat and direct sunlight.   |
|     | Requirements at storerooms and containers:       |  |
|     | Further information on storage conditions:       | No further relevant information available  |
| 7.3 | Specific end uses:                               |  |

**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  | MAK  | 50 ml/m3   | 180mg/m3  |
|     | [75-28-5]   | isobutane | MAK  | 1000 ml/m3 | 2400mg/m3 |
|     | [74-98-6]   | propane   | MAK  | 1000 ml/m3 | 1800mg/m3 |
| 8.2 | Additional information:   |           | The lists valid during the making were used as basis   |            |           |
|     | Personal protective equipment:                                      |           | The usual precautionary measures are to be adhered to when handling chemicals.                                   |            |           |
|     | General protective and hygienic measures:                           |           | Keep away from foodstuffs and beverages. Do not inhale gases/fumes/aerosols.                                     |            |           |
|     | Hand protection   |           | Protective gloves.<br>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.   |            |           |

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**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. -40 °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: 1,2 Vol%, upper 10,9 Vol%  |
| Density:                        | 0.60 (20 °C) g/cm <sup>3</sup>  |
| 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  |

**10. Stability and reactivity**

|      |  |   |
|------|--|---|
| 10.1 | Thermal decomposition / conditions to be avoided |   |
| 10.2 | Possibility of hazardous reactions:              | no information available  |
| 10.3 | 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. |
| 10.4 | Hazardous decomposition products:                | No information available.   |

**11. Toxicological information**

|      |                                       |  |
|------|---------------------------------------|--|
| 11.1 | Acute toxicity: (n-hexane)            | LD50 (oral, rat): 28710 mg/kg (n-hexane)   |
|      | 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. |

**12. Ecological information**

|      |                                       |  |
|------|---------------------------------------|--|
| 12.1 | General information:                  | Do not allow to enter drains/canalization/ground-water   |
| 12.2 | Classification of water endangerment: | The product contains materials that are harmful for the environment. Toxic for aquatic organisms. WGK=2 (polluting substance). |

**13. Disposal considerations**

|      |                 |   |
|------|-----------------|---|
| 13.1 | Product:        |   |
|      | Recommendation: | Use proper landfill disposal or incineration in accordance with local, state and federal regulations. |

