

## Safety data sheet

according to 1907/2006/EC, Article 31

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

- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Product identifier**

- **Trade name:** *gingiva mask*
- **Application of the substance / the mixture** *Product for dental technology*

- **1.3 Details of the supplier of the safety data sheet**

- **Manufacturer/Supplier:**  
*Müller-Omicron GmbH & Co. KG  
Schlosserstr. 1  
D-51789 Lindlar  
GERMANY  
www.mueller-omicron.com*

- **Further information obtainable from:**

*Product safety department  
sds@mueller-omicron.de*

- **1.4 Emergency telephone number:**  
*Mon-Thu: +49 (0)2266 / 4742-0 (8 am - 5 pm CET)  
Fri: +49 (0)2266 / 4742-0 (8 am - 1 pm CET)*

### \* SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
*Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.*

- **2.2 Label elements**

- **Labelling according to Regulation (EC) No 1272/2008**  
*The product is classified and labelled according to the CLP regulation.*

- **Hazard pictograms** *Void*

- **Signal word** *Void*

- **Hazard statements**  
*H412 Harmful to aquatic life with long lasting effects.*

- **Precautionary statements**  
*P101 If medical advice is needed, have product container or label at hand.  
P102 Keep out of reach of children.  
P103 Read carefully and follow all instructions.*

*P273 Avoid release to the environment.*

*P501 Dispose of contents/container in accordance with local/regional/national/international regulations.*

- **Additional information:**  
*This Product contains a substance which is classified as STOT RE 1. Due to its physical form, exposure through inhalation is not expected (Regulation (EC) No 1272/2008 (CLP) - Annex I, 1.1.1.5).*

- **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 characterisation: Mixtures**
- **Description:** *Mixture of substances listed below with nonhazardous additions.*

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- <b>Dangerous components:</b>		
EINECS: 238-455-4	Cristobalite (CAS 14464-46-1) ☠ STOT RE 1, H372	25-50%
CAS: 556-67-2 EINECS: 209-136-7 Index number: 014-018-00-1	octamethylcyclotetrasiloxane ☠ Flam. Liq. 3, H226; ☠ Repr. 2, H361f; ☠ Aquatic Chronic 1, H410 PBT; vPvB	≥0.025-<0.25%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

#### **SECTION 4: First aid measures**

##### **- 4.1 Description of first aid measures**

- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.

##### **- 4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.

##### **- 4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

#### **SECTION 5: Firefighting measures**

##### **- 5.1 Extinguishing media**

- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.

- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

##### **- 5.3 Advice for firefighters**

- **Protective equipment:** No special measures required.

#### **SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.

##### **- 6.2 Environmental precautions:**

Do not allow product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

Do not allow to enter sewers/ surface or ground water.

##### **- 6.3 Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to item 13.

##### **- 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 Precautions for safe handling** No special precautions are necessary if used correctly.

- **Information about fire - and explosion protection:** No special measures required.

##### **- 7.2 Conditions for safe storage, including any incompatibilities**

- **Storage:**

- **Requirements to be met by storerooms and receptacles:** No special requirements.

- **Information about storage in one common storage facility:** Not required.

- **Further information about storage conditions:** None.

- **7.3 Specific end use(s)** No further relevant information available.

#### **SECTION 8: Exposure controls/personal protection**

##### **- 8.1 Control parameters**

- **Additional information about design of technical facilities:** No further data; see item 7.

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**- Ingredients with limit values that require monitoring at the workplace:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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

**- 8.2 Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.

- **Respiratory protection:** Not required.

- **Protection of hands:**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

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 can not be calculated in advance and has therefore to be checked prior to the application.

- **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:** Goggles recommended during refilling

**SECTION 9: Physical and chemical properties**

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

- **General Information**

- **Appearance:**

**Form:** Pasty  
**Colour:** according to product description

- **Odour:** Product specific

- **Odour threshold:** Not determined.

- **pH-value:** Not determined.

- **Change in condition**

**Melting point/freezing point:** Undetermined.

**Initial boiling point and boiling range:** Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gas):** Not applicable.

- **Ignition temperature:** >400 °C

- **Decomposition temperature:** Not determined.

- **Auto-ignition temperature:** Product is not selfigniting.

- **Explosive properties:** Product does not present an explosion hazard.

- **Explosion limits:**

**Lower:** Not determined.

**Upper:** Not determined.

- **Vapour pressure at 20 °C:** 100 hPa

- **Density:** Not determined.

- **Relative density** Not determined.

- **Vapour density** Not determined.

- **Evaporation rate** Not determined.

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- <b>Solubility in / Miscibility with water:</b>	<i>Not miscible or difficult to mix.</i>
- <b>Partition coefficient: n-octanol/water:</b>	<i>Not determined.</i>
- <b>Viscosity:</b>	
<b>Dynamic:</b>	<i>Not determined.</i>
<b>Kinematic:</b>	<i>Not determined.</i>
- <b>Solvent content:</b>	
<b>Organic solvents:</b>	<i>0.0 %</i>
<b>VOC (EC)</b>	<i>0.00 %</i>
<b>Solids content:</b>	<i>42.0 %</i>
- <b>9.2 Other information</b>	<i>No further relevant information available.</i>

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** *No further relevant information available.*
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
*No decomposition if used according to specifications.*
- **10.3 Possibility of hazardous reactions** *No dangerous reactions known.*
- **10.4 Conditions to avoid** *No further relevant information available.*
- **10.5 Incompatible materials:** *No further relevant information available.*
- **10.6 Hazardous decomposition products:** *No dangerous decomposition products known.*

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** *Based on available data, the classification criteria are not met.*
- **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:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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** *Based on available data, the classification criteria are not met.*
- **STOT-repeated exposure** *Based on available data, the classification criteria are not met.*
- **Aspiration hazard** *Based on available data, the classification criteria are not met.*

### \* SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** *No further relevant information available.*
- **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:** *Harmful to fish*
- **Additional ecological information:**
- **General notes:**  
*Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water*  
*Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.*  
*Harmful to aquatic organisms*
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*

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- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### **SECTION 13: Disposal considerations**

- **13.1 Waste treatment methods**
- **Recommendation**  
*Must not be disposed together with household garbage. Do not allow product to reach sewage system.*
- **Uncleaned packaging:**
- **Recommendation:** *Disposal must be made according to official regulations.*

### **SECTION 14: Transport information**

- |   |                 |
|---|-----------------|
| - <b>14.1 UN-Number</b><br>- <b>ADR, IMDG, IATA</b>   | Void            |
| - <b>14.2 UN proper shipping name</b><br>- <b>ADR, IMDG, IATA</b>                           | Void            |
| - <b>14.3 Transport hazard class(es)</b><br>- <b>ADR, ADN, IMDG, IATA</b><br>- <b>Class</b> | Void            |
| - <b>14.4 Packing group</b><br>- <b>ADR, IMDG, IATA</b>                                     | Void            |
| - <b>14.5 Environmental hazards:</b>  | Not applicable. |
| - <b>14.6 Special precautions for user</b>  | Not applicable. |
| - <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>            | Not applicable. |
| - <b>UN "Model Regulation":</b>   | Void            |

### **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.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3, 70
- **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**  
*None of the ingredients is listed.*
- **REGULATION (EU) 2019/1148**
- **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**  
*None of the ingredients is listed.*
- **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**  
*None of the ingredients is listed.*
- **Regulation (EC) No 273/2004 on drug precursors**  
*None of the ingredients is listed.*
- **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**  
*None of the ingredients is listed.*
- **15.2 Chemical safety assessment:** *A Chemical Safety Assessment has not been carried out.*

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**SECTION 16: Other information**

*This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.*

**- Relevant phrases**

*H226 Flammable liquid and vapour.*

*H361f Suspected of damaging fertility.*

*H372 Causes damage to organs through prolonged or repeated exposure.*

*H410 Very toxic to aquatic life with long lasting effects.*

**- Contact:** *sds@mueller-omicron.de*

**- Abbreviations and acronyms:**

*ADR: Accord relatif au transport international 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)*

*VOC: Volatile Organic Compounds (USA, EU)*

*PBT: Persistent, Bioaccumulative and Toxic*

*vPvB: very Persistent and very Bioaccumulative*

*Flam. Liq. 3: Flammable liquids – Category 3*

*Repr. 2: Reproductive toxicity – Category 2*

*STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1*

*Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1*

*Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3*

**- Sources**

*The data for the hazardous ingredients were taken respectively from the last version of Safety Data Sheets of suppliers.*

**- \* Data compared to the previous version altered.**