

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 3D*
- **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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| - Dangerous components: | | |
|--|--|---------------|
| 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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| | |
|--|---|
| - Solubility in / Miscibility with water: | <i>Not miscible or difficult to mix.</i> |
| - Partition coefficient: n-octanol/water: | <i>Not determined.</i> |
| - Viscosity: | |
| Dynamic: | <i>Not determined.</i> |
| Kinematic: | <i>Not determined.</i> |
| - Solvent content: | |
| Organic solvents: | <i>0.0 %</i> |
| VOC (EC) | <i>0.00 %</i> |
| Solids content: | <i>42.0 %</i> |
| - 9.2 Other information | <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

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