

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 05.09.2023

Version number 4

Revision: 02.08.2023

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:**

smartbite, smartbite blackberry, smartbite grey, smartbite speed

Mixture contains components in nanoform

- **Application of the substance / the mixture** bite registration material, medical device

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

- **Manufacturer/Supplier:**

Manufacturer:

Müller-Omicron GmbH & Co. KG
Schlosserstr. 1
D-51789 Lindlar
www.mueller-omicron.com

Exclusive distribution:

Omnident Dental-Handelsgesellschaft mbH
Gutenbergring 7 - 9
D-63110 Rodgau
Phone: +49 (0) 6106 / 874 - 0
Fax: +49 (0) 6106 / 874 - 265
www.smartdent.de
info@smartdent.de

- **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**
The product is not classified, according to the CLP regulation.

- **2.2 Label elements**

- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void

- **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**

This substance/mixture does not contain components classified as either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **Determination of endocrine-disrupting properties**

Endocrine disrupting properties - human health: The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

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Endocrine disrupting properties - Environment: The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

SECTION 3: Composition/information on ingredients

- 3.2 Mixtures

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

- Dangerous components:

| | | |
|-------------------|---|---------|
| EINECS: 238-455-4 | Cristobalite (CAS 14464-46-1) | 50-100% |
| | ☠ STOT RE 1, H372 | |
| | Kieselsäure / silica | 2.5-10% |
| | Nanoform: non-surface-treated nanoforms | |
| | Shape: Spheroidal | |
| | Crystallinity: amorphous nanoform | |
| | Cristobalite (CAS 14464-46-1) | 1-2.5% |
| | ☠ STOT RE 1, H372 | |

- **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

- **General information:** No special measures required.

- **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 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).

- 6.4 Reference to other sections

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.

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SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special measures required.
- **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**
- **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**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Hand protection**
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/face protection** Goggles recommended during refilling

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Fluid
- **Colour:** according to product description
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** Undetermined.
- **Boiling point or initial boiling point and boiling range** Undetermined.

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| | |
|--|--|
| - Flammability | Not applicable. |
| - Lower and upper explosion limit | |
| - Lower: | Not determined. |
| - Upper: | Not determined. |
| - Flash point: | Not applicable. |
| - Auto-ignition temperature: | >290 °C |
| - Decomposition temperature: | Not determined. |
| - pH | Not determined. |
| - Viscosity: | |
| - Kinematic viscosity | Not determined. |
| - Dynamic: | Not determined. |
| - Solubility | |
| - water: | Not miscible or difficult to mix. |
| - Partition coefficient n-octanol/water (log value) | Not determined. |
| - Vapour pressure at 20 °C: | 1 hPa |
| - Density and/or relative density | |
| - Density: | Not determined. |
| - Relative density | Not determined. |
| - Vapour density | Not determined. |
| - Particle characteristics | Kieselsäure / silica: non-surface-treated nanoforms Shape: Spheroidal Crystallinity: amorphous nanoform |

| | |
|--|---|
| - 9.2 Other information | |
| - Appearance: | |
| - Form: | Pasty |
| - Important information on protection of health and environment, and on safety. | |
| - Ignition temperature: | Product is not selfigniting. |
| - Explosive properties: | Product does not present an explosion hazard. |
| - Solvent content: | |
| - Organic solvents: | 0 % |
| - VOC (EC) | 0-<0.01 % |
| - Solids content: | 70.0 % |
| - Change in condition | |
| - Evaporation rate | Not determined. |

| | |
|--|------|
| - Information with regard to physical hazard classes | |
| - Explosives | Void |
| - Flammable gases | Void |
| - Aerosols | Void |
| - Oxidising gases | Void |
| - Gases under pressure | Void |
| - Flammable liquids | Void |
| - Flammable solids | Void |
| - Self-reactive substances and mixtures | Void |
| - Pyrophoric liquids | Void |
| - Pyrophoric solids | Void |
| - Self-heating substances and mixtures | Void |
| - Substances and mixtures, which emit flammable gases in contact with water | Void |
| - Oxidising liquids | Void |
| - Oxidising solids | Void |
| - Organic peroxides | Void |
| - Corrosive to metals | Void |

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- **Desensitised explosives**

Void

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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **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.
- **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.
- **11.2 Information on other hazards**
- **Endocrine disrupting properties**
Endocrine disrupting properties - human health: The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

None of the ingredients is listed.

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.
- **12.5 Results of PBT and vPvB assessment**
This substance/mixture does not contain components classified as either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
Endocrine disrupting properties - Environment: The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

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- **12.7 Other adverse effects**
- **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.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|---|-----------------|
| - 14.1 UN number or ID number | Void |
| - ADR, IMDG, IATA | Void |
| - 14.2 UN proper shipping name | Void |
| - ADR, IMDG, IATA | Void |
| - 14.3 Transport hazard class(es) | Void |
| - ADR, ADN, IMDG, IATA | Void |
| - Class | Void |
| - 14.4 Packing group | Void |
| - ADR, IMDG, IATA | Void |
| - 14.5 Environmental hazards: | Not applicable. |
| - 14.6 Special precautions for user | Not applicable. |
| - 14.7 Maritime transport in bulk according to IMO instruments | 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: 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.

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- 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.

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

H372 Causes damage to organs through prolonged or repeated exposure.

- Contact: sds@mueller-omicron.de

- Date of previous version: 02.03.2023

- 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

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

- 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.

EU