

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

Printing date 20.03.2024

Version number 5 (replaces version 4)

Revision: 20.03.2024

### 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 cola, smartbite bubble gum, 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:**

<b>Manufacturer:</b> Müller-Omicron GmbH & Co. KG Schlosserstr. 1 D-51789 Lindlar www.mueller-omicron.com	<b>Exclusive distribution:</b> 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
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- **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) ☠ STOT RE 1, H372	50-100%
EINECS: 231-545-4	Siliziumdioxid Nanoform: non-surface-treated nanoforms Shape: Spheroidal Crystallinity: amorphous nanoform	2.5-10%
	Kieselsäure / silica Nanoform: non-surface-treated nanoforms Shape: Spheroidal Crystallinity: amorphous nanoform	2.5-10%
	Cristobalite (CAS 14464-46-1) ☠ STOT RE 1, H372	1-2.5%

- **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).

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### - 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 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

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

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

<b>- Information with regard to physical hazard classes</b>	
- <b>Explosives</b>	Void
- <b>Flammable gases</b>	Void
- <b>Aerosols</b>	Void
- <b>Oxidising gases</b>	Void
- <b>Gases under pressure</b>	Void
- <b>Flammable liquids</b>	Void
- <b>Flammable solids</b>	Void
- <b>Self-reactive substances and mixtures</b>	Void

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- <b>Pyrophoric liquids</b>	Void
- <b>Pyrophoric solids</b>	Void
- <b>Self-heating substances and mixtures</b>	Void
- <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
- <b>Oxidising liquids</b>	Void
- <b>Oxidising solids</b>	Void
- <b>Organic peroxides</b>	Void
- <b>Corrosive to metals</b>	Void
- <b>Desensitised explosives</b>	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.

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- **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.
- **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

- |   |                 |
|---|-----------------|
| - <b>14.1 UN number or ID number</b>                                  | Void            |
| - <b>ADR, IMDG, IATA</b>  | Void            |
| - <b>14.2 UN proper shipping name</b>                                 | Void            |
| - <b>ADR, IMDG, IATA</b>  | Void            |
| - <b>14.3 Transport hazard class(es)</b>                              | Void            |
| - <b>ADR, ADN, IMDG, IATA</b>   | Void            |
| - <b>Class</b>  | Void            |
| - <b>14.4 Packing group</b>   | Void            |
| - <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 Maritime transport in bulk according to IMO instruments</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: 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.

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**- 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.

### 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:** 13.11.2023

**- Version number of previous version:** 4

**- 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.**