Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 06.11.2026 Version number 7 Revision: 06.11.2026

*

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 bubble gum**
- **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
sdb@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.
- **Additional information:**
The full text of the classification and labelling elements mentioned is given in Section 16.

- **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**
P273 Avoid release to the environment.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **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.

(Contd. on page 2)

Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 06.11.2026 Version number 7 Revision: 06.11.2026

Trade name: smartBite bubble gum

(Contd. of page 1)

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:**		
	Polymer Aquatic Chronic 3, H412	≥15-<25%
CAS: 68909-20-6 EINECS: 272-697-1 Index number: 014-052-00-7	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products withsilica STOT RE 2, H373, EUH066	≥2.5-<10%
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 (M=10) PBT; vPvB	≥0.01-<0.1%

- **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 section 13.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.

(Contd. on page 3)

Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 06.11.2026 Version number 7 Revision: 06.11.2026

Trade name: smartBite bubble gum

(Contd. of page 2)

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**
- **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:** Wash hands before breaks and at the end of work.
- **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**	Liquid
- **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
- **Flammability**	Not applicable
- **Lower and upper explosion limit**	
- **Lower:**	Not determined
- **Upper:**	Not determined

(Contd. on page 4)

Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 06.11.2026 Version number 7 Revision: 06.11.2026

Trade name: smartBite bubble gum

(Contd. of page 3)

- **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

- **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:**	0.0 %
- **VOC (EC)**	0.00 %
- **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
- **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.

(Contd. on page 5)

Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 06.11.2026 Version number 7 Revision: 06.11.2026

Trade name: smartBite bubble gum

(Contd. of page 4)

- **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.

- **LD/LC50 values relevant for classification:**

Zeolite		
Oral	LD50	>10,000 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rabbit)
Inhalative	LC50/4 h	>18.3 mg/l (rat)

- **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.
- **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.

- **12.7 Other adverse 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.

(Contd. on page 6)

Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 06.11.2026 Version number 7 Revision: 06.11.2026

Trade name: smartBite bubble gum

(Contd. of page 5)

Harmful to aquatic organisms

*

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 or ID 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 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: 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.

(Contd. on page 7)

Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 06.11.2026 Version number 7 Revision: 06.11.2026

Trade name: smartBite bubble gum

(Contd. of page 6)

- **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**

H226 Flammable liquid and vapour.
H361f Suspected of damaging fertility.
H373 May cause damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.
EUH066 Repeated exposure may cause skin dryness or cracking.

- **Contact:** sdb@mueller-omicron.de
- **Date of previous version:** 08.10.2026
- **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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
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 2: Specific target organ toxicity (repeated exposure) – Category 2
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.**