

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

Printing date 09.01.2023

Version number 2

Revision: 09.01.2023

### **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:** Omnibite

- **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 5

D-63110 Rodgau

Phone: +49 (0) 6106 / 874 - 0

Fax: +49 (0) 6106 / 874 - 265

www.omnident.de

info@omnident.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

- **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.

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.

EU

(Contd. on page 2)

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 09.01.2023

Version number 2

Revision: 09.01.2023

Trade name: Omnibite

(Contd. of page 1)

### SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.
- **Dangerous components:** Void
- **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.  
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.

EU

(Contd. on page 3)

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 09.01.2023

Version number 2

Revision: 09.01.2023

Trade name: Omnibite

(Contd. of page 2)

### 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 item 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:**

Transparent

- **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.

- **Flash point:**

Not applicable.

- **Ignition temperature:**

430 °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.

(Contd. on page 4)

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 09.01.2023

Version number 2

Revision: 09.01.2023

**Trade name: Omnibite**

(Contd. of page 3)

- Vapour pressure at 20 °C:	1 hPa
- Density and/or relative density	
- Density at 20 °C:	1.1 g/cm <sup>3</sup>
- Relative density	Not determined.
- Vapour density	Not determined.
<b>- 9.2 Other information</b>	
- Appearance:	
- Form:	Pasty
<b>- Important information on protection of health and environment, and on safety.</b>	
- Auto-ignition temperature:	Product is not selfigniting.
- Explosive properties:	Product does not present an explosion hazard.
- Solvent content:	
- Organic solvents:	0 %
- VOC (EC)	0.00 %
- Solids content:	78.8 %
- Change in condition	
- Evaporation rate	Not determined.
<b>- Information with regard to physical hazard classes</b>	
- 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.
- **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.

(Contd. on page 5)

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 09.01.2023

Version number 2

Revision: 09.01.2023

Trade name: Omnibite

(Contd. of page 4)

- **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**
- **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**
- **ADR, IMDG, IATA** Void

(Contd. on page 6)

EU

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 09.01.2023

Version number 2

Revision: 09.01.2023

Trade name: Omnibite

(Contd. of page 5)

- 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: 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.

### 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.

- Contact: sds@mueller-omicron.de

- Date of previous version: 03.05.2021

- 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

(Contd. on page 7)

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

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**Trade name: Omnibite**

(Contd. of page 6)

*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***- 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.**

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