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

Printing date 10.07.2024 Version number 4 Revision: 11.06.2024

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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: DC Bite NF, DC Bite Apple**
- **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:	Exclusive distribution:
Müller-Omicron GmbH & Co. KG	DC DentalCentral GmbH
Schlosserstr. 1	Owiedenfeldstr. 6
D-51789 Lindlar	D - 30559 Hannover
www.mueller-omicron.com	Phone: +49 (0) 4154 / 8437 - 0
	Fax: +49 (0) 4154 / 8437 - 33
	info@dental-central.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)

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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.

Endocrine disrupting properties - Environment: The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or

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Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

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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%
	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).
- **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.

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- ***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*

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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.*
- ***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.*

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- **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 %
- **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
- **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.

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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.

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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.

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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: 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**
H372 Causes damage to organs through prolonged or repeated exposure.
- **Contact:** sds@mueller-omicron.de
- **Date of previous version:** 13.11.2023

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- ***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.***