



Safety Data - Wax bite registrations, bite registrations, bite rims

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Issue date: 12/11/2015 Revision date: 01/30/2023 Supersedes: 08/30/2024 Version: 2.1
SDS No: 11294-0006

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form: Mixture
Product name: neutral and flavored bite waxes and bite rims for partial and full dentures
other means of identification: Medical devices for short-term use on patients

Bite-receiving wax sticks with aroma	63100	63200	63400	63500	63700	63800
Bite-receiving wax sticks without aroma	82100	82200	82400	82500	82600	82700
Bite-receiving wax plates without aroma	81800	81900				
Bite rims preformed with aroma	62100	62200	62300	62400	62500	
Bite rims preformed without aroma	82300	82350	82800	82850	82900	
Bite rims XXL, large, hard with Aroma	62600					
Bite registration wax, hard with aroma	84300					
Metal foil wax without aroma	84200					

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture : Application in dental healthcare (Consumables)

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

gebdi Dental-Products GmbH
Industriestrasse 3a
78234 Engen
Germany
T +49 7733-9410-69 - F +49 7733-6434

1.4. Emergency telephone number

Emergency Number: 0049-7733-9410-16 (Mo-Th 8.00 -12.00/13.00-16.30 Fr.8.00-12.00/13.00-15.00)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.



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2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Chemical characterization : Mixture of different waxes with additives

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Call a poison center or a doctor if you feel unwell.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Wash with water and soap as a precaution.
First-aid measures after eye contact	: Rinse eyes with water as a precaution. Remove contact lenses, if present and easy to do. Continue rinsing.
First-aid measures after ingestion	: Do not induce vomiting. Rinse mouth. Drink plenty of water. Call a poison center or a doctor if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Water spray. Dry powder. Foam.
Unsuitable extinguishing media	: Do not use a solid water stream as it may scatter and spread fire.



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5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information : Vapours are heavier than air and may spread along floors.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Get unprotected persons to safety. Remove ignition sources.

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Do not discharge into the drains/surface waters/groundwater.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Mechanically recover the product.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". Information for disposal see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool. Keep away from heat and direct sunlight.
Information on mixed storage : Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

See Section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available



Safety Data - Wax bite registrations, bite registrations, bite rims

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8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:

Safety goggles with side protection (EN 166).

8.2.2.2. Skin protection

Skin and body protection:

Long sleeved protective clothing (DIN EN ISO 6530). General protective and hygienic measures

Hand protection:

Chemically resistant protective gloves. Requirements can vary as a function of the use. Therefore it is necessary to adhere additionally to the recommendations given by the manufacturer of protective gloves

Hand protection					
Type	Material	Permeation	Thickness (mm)	Penetration	Standard
protective gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,4		EN ISO 374

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: According to product specification.
Odour	: Slight.
Odour threshold	: Not available
Melting point	: Not determined.
Freezing point	: Not applicable
Boiling point	: Not available
Flammability (solid, gas)	: Non flammable.
Explosive properties	: Product is not explosive.
Explosive limits	: Not applicable
Lower explosive limit (LEL)	: Not determined.
Upper explosive limit (UEL)	: Not determined.

Wax-Special waxes

Safety Data Sheet

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Version: 3.0 SDS No: 11294-0006

Flash point	: > 140 °C
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not determined.
Viscosity, dynamic	: > 50 mPa.s
Solubility	: Water: partly miscible
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: 0.9 g/cm³ @ 20 °C
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

Strong oxidizing agent.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)

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Version: 3.0 SDS No: 11294-0006

STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute)	: Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Based on available data, the classification criteria are not met)

12.2. Persistence and degradability

No additional information available

12.3. Bio accumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions. The waste code/waste name refers to the end product. To be defined by the customer in agreement with appropriate waste disposal company.
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SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated

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Version: 3.0 SDS No: 11294-0006

ADR	IMDG	IATA	ADN	RID
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

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Safety Data Sheet

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Version: 3.0 SDS No: 11294-0006

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

All chapters have been modified since the previous version.

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor
ATE	Acute Toxicity Estimate
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
DOT	Department of Transport
TDG	Transportation of Dangerous Goods
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
IARC	International Agency for Research on Cancer
vPvB	Very Persistent and Very Bioaccumulative
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
IBC-Code	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
MARPOL 73/78	MARPOL 73/78: International Convention for the Prevention of Pollution From Ships
ADG	Transport of Australian Dangerous Goods
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
LC50	Median lethal concentration

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Abbreviations and acronyms:	
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
ED	Endocrine disrupting properties

Other information

Data of sections 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities. The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge. The delivery specifications are contained in the corresponding product sheet. This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should therefore not be construed as guaranteeing any specific property of the product.