according to REACH Regulation (EC) No. 1907/2006 including amending Regulation (EU) 2020/878

YETI Dentalprodukte GmbH

Revised on: December 11, 2015 Replaces: January 30, 2023 Revision No.: 2.0

Wax – Full and Partial Dentures / Bite Registrations

(Sheet Waxes, Metal Foil Waxes, Flavored Bite Waxes / Rims)

11294-0006



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

Wax – Full and partial dentures / bite registration waxes (Sheet waxes, metal foil waxes, flavored and neutral bite waxes / ridges) m. A. = with flavor / o. A. = without flavor

1.1. Product Identifier: Name / Article Number

Product Form: Mixtures

Metal Foil Wax 605-0060 Bite Registration with A. 606-2000

Bite Rims with A. 610-0100, 611-0100, 612-0100, 613-0100

Bite Rims without A. 614-0100

Bite Waxes with A. 612-0490, 612-1850, 613-0490, 613-1850, 614-0490, 614-1850

SPECIAL 650-0500, 650-2500, 652-0500, 652-2500, 653-0500, 653-2500, 655-0500

655-2500

SUPERPINK 660-0500, 660-2500

SOLIDUS 80 680-0000 SOLIDUS 84 684-0000

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

Use of the substance/mixture

Waxes for the manufacture of crowns and bridges, model casting, and reconstructions

1.2. Details of the supplier of the safety data sheet

Company name: YETI Dentalprodukte GmbH

Street: Industriestraße 3 City: D-78234 Engen Telephone: +49 7733-9410-0 Fax: +49 7733-9410-22

Information department: sdb@yeti-dental.com

1.4. Emergency number: +49 7733-9410-0 (Mon-Thurs 8:00 - 16:30, Fri 8:00 - 15:00)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

The mixture is not classified as hazardous according to Regulation (EC) No. 1272/2008

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2.2. Label elements

Advice on labeling according to Regulation (EC) No. 1272/2008 [CLP]

This product is not subject to labeling requirements under EC directives.

2.3 Other hazards

According to Regulation (EC) No. 1907/2006 (REACH), this product does not contain any PBT/vPvB substances. Assessed according to REACH Annex XIII.

The mixture does not contain any substances listed for endocrine-disrupting properties according to REACH Article 59(1), or it has been determined according to the criteria of Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 not to contain any substances with endocrine-disrupting properties at a concentration of 0.1% or higher.

SECTION 3: Composition/Information on Ingredients

3.1. Substances not applicable

3.2. Mixtures

Chemical Characterization

Mixture of various waxes with additives

This mixture does not contain any substances subject to notification according to the criteria in Section 3.2 of Annex II to the REACH Regulation.

SECTION 4: First Aid Measures

4.1. Description of First Aid Measures

General Information

In case of accident or if you feel unwell, seek medical advice.

In case of inhalation

If used as intended, no exposure through inhalation is expected.

In case of skin contact

Wash with soap and plenty of water. If skin irritation persists, seek medical advice.

In case of eye contact

Remove contact lenses. Rinse immediately with plenty of water, including under the eyelids, for at least 15 minutes

Seek ophthalmic treatment.

In case of swallowing

Do not induce vomiting. Rinse mouth and drink plenty of water. Never give anything by mouth to an unconscious person. Consult a doctor if you feel unwell. Do not allow the person to drink a neutralizing agent.

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

When handled as directed, no adverse health effects are known or expected.

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

Alcohol-resistant foam, dry chemical, carbon dioxide (CO2), water spray.

Unsuitable extinguishing media:

Full water jet.

5.2. Special hazards arising from the substance or mixture:

Fire may produce: Carbon monoxide and carbon dioxide. Vapors are heavier than air and will spread along ground. Flashback possible over long distances.

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5.3. Advice for firefighters

Use self-contained breathing apparatus. Wear protective clothing.

Additional information

Cool endangered containers with a water spray. Do not use a full water jet.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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

6.1.1 Non-emergency personnel

Emergency procedures: Ventilate contaminated areas.

6.1.2 For emergency responders

Protective equipment: Do not attempt to work without protective equipment. See Section 8 for further information.

Exposure controls/Personal protection.

6.2. Environmental precautions

Do not empty into drains/surface water/groundwater.

6.3. Methods and materials for containment and cleaning up

Collect mechanically and place in suitable containers for disposal.

6.4. Reference to other sections

Observe protective measures (see Section 8 "Exposure Control/Personal Protection").

For disposal information, see Section 13.

SECTION 7: Handling and Storage

7.1. Precautions for safe handling

Advice on safe handling/hygiene measures

Do not leave vessels/containers open. Observe generally accepted hygiene measures. Do not eat, drink, or smoke when using the product. Wash hands before breaks and at the end of work.

Advice on fire and explosion protection

No special fire protection measures required.

Requirements for storage rooms and containers

7.2. Conditions for safe storage, including any incompatibilities

No special measures required.

Advice on joint storage

Keep away from foodstuffs, beverages, and animal feed. Do not store together with oxidizing or self-igniting materials.

Storage class (LGK): LGK13 - Non-combustible solids

Further information on storage conditions

Store in a well-ventilated area. Store in a cool, well-ventilated place. Keep container tightly closed.

Protect from heat and direct sunlight.

7.3. Specific end use(s)

Waxes for the fabrication of crowns and bridges, model castings, and reconstructions

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SECTION 8: Exposure Controls/Personal Protection

8.1. Control Parameters

8.1.1 National Occupational Exposure Limits and Biological Limit Values

No additional information available

8.1.2 Recommended Monitoring Procedures

No additional information available

8.1.4 DNELs and PNECs

No additional information available

8.1.5 Control Banding

No additional information available

8.2. Exposure Controls

8.2.1 Appropriate Engineering Controls

Ensure adequate ventilation. Ensure adequate air exchange and/or exhaust ventilation in work areas.

8.2.2 Personal Protective Equipment

8.2.2.1 Eye/Face Protection

Tightly fitting safety goggles (EN 166).

8.2.2.2. Hand Protection

Butyl chemical protective gloves, minimum thickness 0.4 mm, breakthrough time (wearing time >480 minutes) according to EN ISO 374.

Depending on the application, different requirements may apply. Therefore, the recommendations of the protective glove supplier must also be observed.

Body Protection

Long-sleeved work clothing (DIN EN ISO 6530). Wear full-body, flame-retardant clothing.

Respiratory Protection

If vapors/mist are generated, use respiratory protection (full-face mask, filter A).

Environmental Exposure Controls

Avoid release to the environment.

SECTION 9: Physical and Chemical Properties

9.1. Information on Basic Physical and Chemical Properties

State: Solid

Color: According to product description

Odor: Faint

Odor threshold not available

Melting point: n.a.

Initial boiling point and boiling range: n.a.

Softening point: n.a.
Dropping point: 70 - 110 °C
Flash point: > 140 °C
Autoignition temperature: n.a.

Autoignition temperature: n.a. Decomposition temperature: n.a.

Explosion hazards: The product is not explosive.

Density (at 20 °C): 0.9 g/cm³

Relative density: n.a.

Relative vapor density at 20 °C: n.a. Water solubility: Partially miscible Dyn. viscosity: (at 20 °C) > 50 mPa s

9.2. Other information

9.2.1 Information on physical hazard classes

No data available.

9.2.2 Other safety parameters

No data available

(n.a. - not applicable, n.a. - not determined)

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SECTION 10: Stability and Reactivity

10.1. Reactivity

No decomposition under normal storage, use, and transport conditions.

Polymerization with evolution of heat.

10.2. Chemical Stability

Chemically stable under normal conditions.

10.3. Possibility of Hazardous Reactions

No hazardous reactions are known under normal conditions of use.

10.4. Conditions to Avoid

Protect from heat and direct sunlight.

10.5. Incompatible Materials

Strong oxidizing agents.

10.6. Hazardous Decomposition Products

No hazardous decomposition products are known under normal storage and use conditions.

SECTION 11: Toxicological Information

11.1. Information on Hazard Classes according to Regulation (EC) No. 1272/2008

Acute Toxicity (oral):

Acute toxicity (dermal):

Acute toxicity (inhalation):

Acute toxicity (inhalation):

Acute toxicity (inhalation):

Skin corrosion/irritation:

Serious eye damage:

Not classified. Based on available data, the classification criteria are not met.

Not classified. Based on available data, the classification criteria are not met.

Not classified. Based on available data, the classification criteria are not met.

Not classified. Based on available data, the classification criteria are not met.

Not classified. Based on available data, the classification criteria are not met.

Respiratory sensitization: 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.

STOT-single exposure: Not classified. Based on available data, the classification criteria are not met.

Specific target organ toxicity (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 further information available

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SECTION 12: Ecological Information

12.1. Toxicity

General Ecology: The product is not considered harmful to aquatic organisms nor does it cause long-term environmental damage.

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 further information available.

12.3. Bioaccumulative Potential

No further information available.

12.4. Mobility in Soil

No further information available.

12.5. Results of PBT and vPvB Assessment

No further information available.

12.6. Other Adverse Effects

No further information available.

12.7. Other Adverse Effects

No further information available.

SECTION 13: Disposal Considerations

13.1. Waste treatment methods

Waste treatment methods:

Dispose of contents/container according to the sorting instructions of the authorized waste collector. The waste code/waste name refers to the final product. To be determined by the customer in consultation with an appropriate waste disposal company.

SECTION 14: Transpo	rt information					
According to ADR/IMDG/IATA/ADN/RID						
	ADR	IMDG	IATA	ADN	RID	
14.1 UN number or ID nu	umber					
	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	
14.3. Transport hazard c	lasses					
	Not regulated	Not regulated	Not regulated	Not regulated	Not regulated	
14.4. Packaging group						
	Not regulated	Not regulated	Not regulated	Not regulated	Not regulated	
14.5. Environmental haza	ards					
	Not regulated	Not regulated	Not regulated	Not regulated	Not regulated	
No additional information	available				·	

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14.6. Special precautions for user

Land transport not regulated
Marine transport not regulated
Air transport not regulated
Inland waterway transport not regulated
Rail transport not regulated

14.7. Bulk maritime transport according to IMO instruments

Not applicable. Not classified as dangerous goods under transport regulations.

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 (Restrictions List)

Contains no substances listed in REACH Annex XVII (Restrictions List).

REACH Annex XIV (Authorization List)

Contains no substances listed in REACH Annex XVII (Authorization List).

REACH Candidate List (SVHC)

Contains no substances listed on the REACH Candidate List.

PIC Regulation (Prior Informed Consent)

Does not contain any substances listed on the PIC list (Regulation EU 649/2012 concerning the export and import of dangerous chemicals).

POP Regulation (Persistent Organic Pollutants)

Does not contain any substances listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants).

Ozone Regulation (1005/2009)

Does not contain any substances listed on the Ozone Depletion List (Regulation EU 1005/2009 on substances that deplete the ozone layer).

Explosives Precursors Regulation (EU 2019/1148)

Does not contain any substances listed on the Explosives Precursors List (Regulation EU 2019/1148 on the marketing and use of explosives precursors).

Drug Precursors Regulation (EC 273/2004)

Contains no substances listed on the list of drug precursors (EC Regulation 273/2004 on drug precursors).

15.1.2 National regulations

Germany

Employment restrictions: Observe restrictions according to the Maternity Protection Act (MuSchG).

Observe restrictions according to the Youth Employment Protection Act (JArbSchG).

Water hazard class (WGK): WGK2, Significantly hazardous to water (classification according to AwSV, Annex 1) Major Accident Ordinance (Section 12 of the Federal Immission Control Act): Not subject to the Major Accident Ordinance (Section 12 of the Federal Immission Control Act).

15.2 Chemical Safety Assessment

A chemical safety assessment has not been conducted.

SECTION 16: Other information

Revisions: All sections have been revised compared to the previous version.

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Abbreviations and Acronyms

ADN European Agreement concerning	g the International Carriage of Dang	gerous Goods by Inland Waterways

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road

BKF Bioconcentration Factor

ATE Acute Toxicity Estimate

DMEL Derived Minimal Effect Level

DNEL Derived No Effect Level

IATA International Carriage of Dangerous Goods by Air

IMDG International Maritime Dangerous Goods

RID Regulations concerning the International Carriage of Dangerous Goods by Rail

DOT Department of Transportation

TDG Transport of Dangerous Goods

REACH Registration, Evaluation, Authorisation and Restriction of Chemicals, Regulation (EC) No. 1907/2006

GHS Globally Harmonized System of Classification and Labelling of Chemicals

IARC International Agency for Research on Cancer

vPvB very persistent and very bioaccumulative

PBT Persistent, Bioaccumulative and Toxic

PNEC Predicted No Effect Concentration

IBC- Internal Safety Regulation for the Carriage of Dangerous Chemicals and Harmful Liquids in Bulk by Maritime Transport

CLP Classification, Labelling and Packaging Regulation, Regulation (EC) No. 1272/2008

MARPOL MARPOL 73/78: The International Convention for the Prevention of Marine Pollution from Ships

ADG Australian Transport of Dangerous Goods

BLV Biological Limit Value

BOD Biochemical Oxygen Demand (BOD)

COD Chemical Oxygen Demand (COD)

EC No. European Community Number

EC50 Mean Effective Concentration

EN European Standard

LC50 Lethal Concentration (LD50) Median Lethal Dose (LOAEL)

NOAEC No Observed Adverse Effect Concentration

NOAEL No Observed Adverse Effect Dose

NOEC No Observed Adverse Effect Concentration

OECD Organisation for Economic Co-operation and Development

OEL Workplace Exposure Limit

SDS Safety Data Sheet

STP Wastewater Treatment Plant

THOD Theoretical Oxygen Demand (ThOD)

TLM Median Tolerance Limit

VOC Volatile Organic Compounds

CAS Chemical Abstract Service Number

N.O.S. Not Otherwise Specified

ED Endocrine Disrupting Properties

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Further information

Some of the information in positions 4 to 8 and 10 to 12 does not relate to the use and proper application of the product (see package leaflet/technical information), but rather to the risk of large quantities being released in the event of accidents or irregularities.

This information describes exclusively the safety requirements of the product(s) and is based on our current knowledge.

The delivery specifications can be found in the respective product data sheets.

It does not constitute a guarantee of the properties of the described product(s) within the meaning of statutory warranty regulations.

This information is based on our current knowledge and is intended to describe the product only with regard to health, safety, and environmental conditions. It must therefore not be interpreted as a guarantee for specific properties of the product.