

1. PRODUCT AND COMPANY IDENTIFICATION
1.1 Product Identifier

Product Name: Patient Relief Wax; Ortho Wax Bites; Laminated Bite Wafers; Silicone Relief Wax

Common Name: Orthodontic Supplies - Dental Wax

Material: Wax

Restrictions on Use: American Orthodontics' products are used for the treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist. Federal law restricts this device to use by or on the order of a dentist or orthodontist.

EC No.: None

REACH Registration No.: None

CAS No. / IUPAC: None

1.2 Relevant Identified Uses/ Uses Advised Against

Relevant identified uses: Dental/Orthodontic use only

Uses advised against: Not for Consumer use. Please see "Restrictions on Use"

1.3 Details of the Supplier of the Safety Data Sheet
Company Name:

American Orthodontics
 3524 Washington Avenue
 Sheboygan, WI 53081
 Phone: 920-457-5051
 Fax: 920-457-1485

E-mail: info@americanortho.com

National Contact: Safety Department

1.4 Emergency Telephone Number
Emergency Response Number:

920-457-5051

Only available during office hours: 8:00AM – 5:00PM (Central Time)

Language of Phone Service: English

2. HAZARDS IDENTIFICATION
General Hazards Statement:

This product is a manufactured article as defined under REACH. No labeling is required for finished product.

This product is classified as "articles" and do not constitute a hazardous material in solid form und the definitions of the OSHA Hazard Communication Standard (29CFR1910.1200). Any articles manufactured from these solid products would be generally classified as non-hazardous.

Not hazardous when used in accordance with the relevant identified uses. Above its melting point, wax becomes a liquid and flows more readily as its temperature increases. If material becomes a hot liquid, it requires special handling. At temperatures significantly above its melting point, hydrocarbon vapors are given off which should be handles with adequate ventilation. Can cause eye, skin and respiratory irritation.

3. COMPOSITION / INFORMATION ON INGREDIENTS

No classified ingredients present

4. FIRST-AID MEASURES

4.1 Description of First-Aid Measures

General Notes

Material as supplied is non-hazardous. When used as intended, it is not expected to cause adverse reactions with respect to inhalation, dermal (eye/skin), and ingestion exposure routes; however if exposed to melted wax, consider the following:

Inhalation

Move victim to fresh air. Call a physician if symptoms persist

Skin Contact

Exposure to fumes vapor and smoke from thermal degradation can cause skin irritation. Exposure to molten material can cause burns. Run exposed area under water for 15 minutes, then contact a physician. Do not attempt to remove material bonded to skin.

Eye Contact

Exposure to fumes vapor and smoke from thermal degradation can cause irritation. Direct contact with molten material will cause eye injury. Flush eyes with copious amounts of water for 15 minutes, administer first aid, and call a physician.

Ingestion/Swallowing

Ingestion of molten wax is not a likely route of exposure.

Self-Protection of First-Aider

Use protective gloves and suitable protective clothing when dealing with molten product.

4.2 Important Symptoms and Effects

Delayed effects may occur if molten product is inhaled. Keep person under medical observation for 48 hours.

4.3 Medical Attention & Special Treatment Necessary

For eye/skin contact, flush affected area with cold water for at least 15 minutes. Remove any affected articles of clothing. If ingested or inhaled, seek immediate medical attention; molten product may cause thermal burns. Molten wax is non-toxic.

Notes to the Doctor:

Delayed effects may occur if molten product is inhaled. Keep person under medical observation for 48 hours. Treat all thermal injuries symptomatically.

5. FIRE AND EXPLOSION HAZARDS

Extinguishing Media: Carbon dioxide, foam and dry chemicals

Unsuitable Extinguishing Media: Do not use direct water stream

Specific Hazards Arising from the Chemical: Standard combustion products

Protective Equipment and Precautions for Firefighters: Standard protection for all firefighters stated in this subsection of the SDS text should include self-contained breathing apparatus (SCBA) and full firefighting turn-out gear (Bunker gear)

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment, and Emergency Procedures: Use personal protective equipment recommended in Section 8

Methods for Containment and Clean-up: Handle as plastic material. Allow molten material to cool before clean up.

Other Information: None Noted

7. HANDLING AND STORAGE

7.1 Precautions for Safe-Handling

Use with adequate ventilation, do not use near ignition sources

7.2 Conditions for Safe Storage, Including Any Incompatibilities

Store in cool, dry location away from ignition sources. Use appropriate personal protective equipment when handling molten material.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control Parameters

No data available but non-toxic.

8.2 Exposure Controls

8.2.1 Appropriate Engineering Controls

None needed if used at room temperature. If material is in a molten state, wear appropriate personal protective equipment (thermal gloves, safety glasses and an apron/splash guard). If molten, ensure adequate ventilation.

8.2.2 Personal Protective Equipment

8.2.2.1 Eye & Face Protection

- WHEN MOLTEN ONLY: Wear face shield or chemical splash goggles

8.2.2.2 Skin Protection

Hand Protection

- WHEN MOLTEN ONLY: Wear gloves impervious to this material

Other Skin Protection

- WHEN MOLTEN ONLY: Wear long sleeves and protective clothing to minimize skin contact.

8.2.2.3 Respiratory Protection

- None Required

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Basic Physical & Chemical Properties

Appearance:	White solid
Odor:	Mild
Odor Threshold:	N/A
pH:	N/A
Melting Point:	No data
Boiling Point:	>230°C
Solubility(ies):	In water: Insoluble

10. STABILITY AND REACTIVITY

10.1 Reactivity

Not Reactive

10.2 Chemical Stability

Stable

10.3 Conditions of Instability

N/A

10.4 Possibility of Hazardous Reactions

N/A

10.5 Conditions to Avoid

Avoid strong oxidizing agents like peroxides and chlorines

10.6 Incompatible Materials

None

10.7 Hazardous Decomposition Products

Will decompose into Carbon dioxide, monoxide and other ketones and aldehydes when heated well above its boiling point

10.8 Hazardous Polymerization

Will not occur.

11. TOXICOLOGICAL INFORMATION

Likely Route of Exposure: Dermal (eye/skin), inhalation, ingestion – wax is not hazardous

Eye Contact: Can cause slight mechanical irritation

12. ECOLOGICAL INFORMATION

12.1 Ecotoxicity: Material is not considered harmful to the environment

12.2 Persistence and Degradability: Not Known

12.3 Bio accumulative Potential: Will not bioconcentrate in fish and aquatic organisms nor will it adsorb to sediment and suspended organic matter

12.4 Mobility in Soil: None Known

This product does not contain persistent, bioaccumulative and toxic chemicals (PBTs) nor does this product contain any very persistent and very bioaccumulative chemicals (vPvBs)

13. DISPOSAL CONSIDERATIONS

The generator of waste material has the responsibility for proper waste classification, transportation and disposal with accordance applicable federal, state/provincial and local regulations.

14. TRANSPORTATION INFORMATION

Not hazardous for transportation

15. REGULATORY INFORMATION

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

All ingredients conform to the EU requirements

National Regulations (USA):

SARA Sections 302 & 304: This product does not contain Extremely Hazardous Substances (EHS) and is not subject of emergency planning requirements

CERCLA: This product does not contain CERCLA Hazardous Substances and is not subject to reporting requirements

SARA Section 313: Substances within this product are not required to be reported in accordance with SARA 313 or the substances within are exempt by rules for “de minimis concentrations of a toxic chemical mixture” §372.38(a)

US (TSCA): Components within this product are included on the TSCA Inventory of Chemical Substances

California Proposition 65: There are no chemicals within this mixture on the Proposition 65 List

International Regulations:

Canada (DSL): All ingredients are on the inventory or exempt from listing

Japan (ENCS): All ingredients are on the inventory or exempt from listing

15.2 Chemical Safety Assessment:

No chemical safety assessment has been carried out for this substance/mixture by the supplier.

16. ADDITIONAL INFORMATION

16.1 Indication of changes/revision to SDS:

1. New format
2. Inclusion of EC Requirements
3. **Revision Date:** 09/15/2015

16.2 Abbreviations and acronyms:

None

16.3 Key literature references and sources for data

1. Guidance on the Compilation of Safety Data Sheets; European Chemical Agency (ECHA); Version 2.1, February 2014
2. Regulation (EC) No 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling, and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

16.4 Classification and procedure used to derive classification for mixtures according to Regulation (EC) 1272/2008[CLP]:

None

Some of the information presented and conclusions drawn herein are from sources other than direct test data on the product itself. The information in the SDS was obtained from sources that we believe are reliable and is believed to be valid and accurate. American Orthodontics, however, makes no warranty, express or implied, regarding its correctness of the information provided. The conditions or method of handling, storage, use and disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage, or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. If the product is used as a component in another product or used in a way other than recommended by the Company, this SDS information may not be applicable. **Reasonable safety precautions must always be observed.**