DENTSPLY International

Safety Data Sheet

Safety Data Sheet (conforms to with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 2015/830), US 29CFR1910.1200, Canada Hazardous Products Regulation

Date Issued: 13 October 1997 Document Number: 115 Date Revised: 27 March 2017 Revision Number: 6

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled): Truwax® Baseplate Wax (Regular)

Part/Item Number: 7709002, 7709003

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use: Used in construction of artificial dentures

Restrictions on Use: For Professional Use Only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: Dentsply Sirona Prosthetics

Manufacturer/Supplier Address: 570 West College Ave.

York, PA 17401

Manufacturer/Supplier Telephone Number: 717-845-7511 (Product Information)

Email address: Prosthetics MSDS@Dentsplysirona.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number: 800-424-9300 Chemtrec

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

| GHS Classification: | | |
|----------------------------|---------------|---------------|
| Health | Environmental | Physical |
| Not Hazardous | Not Hazardous | Not Hazardous |

2.2 Label Elements:

None Required

Signal Word: None

| Hazard Phrases | Precautionary Phrases | |
|----------------|-----------------------|--|
| None Required | None Required | |

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

| Hazardous Components | C.A.S. # | EINECS # / REACH Registration # | Classification | WT % |
|------------------------------|----------|---------------------------------|----------------|-------|
| Paraffin Wax | Mixture | Mixture | Not Applicable | 40-70 |
| Non-hazardous Wax and Resins | Mixture | Mixture | Not Applicable | 30-60 |

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS Classifications.

4. FIRST AID MEASURES

| 4.1 Descripti | on of First Aid Measures: |
|---------------|---|
| Eye | Flush victim's eyes with water, while holding the eyelids apart. Get medical attention if irritation persists. If product is hot, flush eyes with large quantities of water, while holding the eyes lids apart. Get immediate medical attention. |
| Skin | Wash skin with soap and water. If product is molten, cool skin with large amounts of water. Do not remove material bonded to the skin. Do not apply salves or ointment. Get immediate medical attention. Launder clothing before re-use. |
| Inhalation | In solid form, no adverse effects are expected. If vapors or fumes from molten material are inhaled and irritation or symptoms occur, remove victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration. Get medical attention if irritation or symptoms occur. |
| Ingestion | If small quantities are swallowed, rinse out mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious or drowsy person. If large amounts are swallowed or if irritation or discomfort occurs, get medical attention. |

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

Vapors or fumes from molten material may cause eye and respiratory tract irritation. Contact with molten product may cause thermal burns.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

Immediate medical attention is required when in contact with molten material.

5. FIRE-FIGHTING MEASURES

| 5.1 Extinguishing Media: | Use water fog, carbon dioxide, foam, or dry chemical. |
|--------------------------|---|
|--------------------------|---|

5.2 Special Hazards Arising from the Substance or Mixture:

Contact with molten product may cause thermal burns. Decomposition may release carbon monoxide, carbon dioxide, and smoke.

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures/Precautions for Fire Fighters: No special precautions required. Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Avoid contact with skin, eyes or clothing.

6.2 Environmental Precautions:

Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

At ambient temperatures, pick up material and place into a container for disposal. If molten, allow material to solidify and cool. Pick up or scrape up and place into a containers for disposal.

6.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handing:

Avoid contact with molten material. Avoid breathing vapors or fumes. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation.

Empty containers retain product residues. Follow all SDS precautions when handling empty containers.

- **7.2 Conditions for Safe Storage, Including Any Incompatibilities:** Store in a dry, well-ventilated area away from heat, direct sunlight and all sources of ignition.
- **7.3 Specific End Use (s):** For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

| Paraffin Wax (As Paraffin Wax Fume) | 2 mg/m³ TWA ACGIH TLV | |
|--|----------------------------------|--|
| | Belgium: 2 mg/m³ TWA | |
| | 2 mg/m³ TWA, 6 mg/m³ STEL UK-WEL | |
| Non-hazardous Waxes and Resins (As Paraffin Wax Fume) | 2 mg/m³ TWA ACGIH TLV | |
| | Belgium: 2 mg/m³ TWA | |
| | 2 mg/m³ TWA, 6 mg/m³ STEL UK-WEL | |
| Biological Exposure Limits: None Established | | |
| | | |

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate general or local exhaust ventilation to minimize exposures levels.

Individual Protection Measures (PPE):

Specific Eye/face Protection: None needed if handling product at ambient temperatures. Wear safety glasses when handling hot material.

Specific Skin Protection: None needed if handing product at ambient temperatures. Wear insulated gloves when handling hot material. Consult glove supplier for thickness and breakthrough times.

Specific Respiratory Protection: None under normal use conditions. If the product is heated and ventilation is inadequate, wear an approved respirator appropriate for the exposure conditions. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice.

Specific Thermal Hazards: Clothing with long sleeves should be worn when working with molten product.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

| Appearance: | Pink wax solid | Explosive limits: | LEL: 0.9% (paraffin) UEL: 7.0% (paraffin) |
|--|------------------------|---|--|
| Odor: | Pleasant natural odor. | Vapor pressure (mmHg): | <1 mmHg |
| Odor threshold: | Not applicable | Vapor density: | >1 |
| рН: | Not applicable | Relative density: | 0.9 |
| Melting/freezing point: | 153°F (67°C) | Solubility(ies): | Negligible |
| Initial boiling point and boiling range: | Not applicable | Partition coefficient: n-octanol/water: | Not applicable |
| Flash point: | >500°F (>260°C) COC | Auto-ignition temperature: | Not available |
| Evaporation rate: | Not applicable | Decomposition temperature: | Not available |
| Flammability (solid, gas): | Not applicable | Viscosity: | Not applicable |

| Explosive Properties: | Non-explosive | Oxidizing Properties: | None |
|-----------------------|---------------|-----------------------|------|
|-----------------------|---------------|-----------------------|------|

9.2 Other Information: None available.

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.

10.2 Chemical Stability: Stable

10.3 Possibility of Hazardous Reactions: Hazardous polymerization will not occur. Material will cause thermal burns if exposed to direct sunlight or high temperatures.

10.4 Conditions to Avoid: Avoid extreme heat (>300°F (>148.9°C)), direct sunlight or high temperatures.

10.5 Incompatible materials: Avoid oxidizing agents.

10.6 Hazardous Decomposition Products: Thermal decomposition may release carbon monoxide, carbon dioxide, and smoke.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Vapors or fumes may cause eye irritation with redness and tearing. Contact with molten product may cause thermal

Skin: Contact with molten product may cause thermal burns.

<u>Ingestion:</u> Small amounts are not anticipated to cause adverse effects. Large quantities may cause obstruction of the bowel.

<u>Inhalation:</u> Inhalation of vapors or fumes may cause irritation of the eyes, nose and upper respiratory tract. Symptoms include coughing, sneezing and difficulty in breathing.

Chronic Health Effects: None known.

Irritation: No data available. This product is not expected to cause eye or skin irritation.

Corrosivity: No data available. This product is not expected to be corrosive.

Sensitization: No data available. This product is not expected to cause sensitization.

<u>Carcinogenicity:</u> None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

Mutagenicity: No data available. This product is not expected to cause mutagenic activity.

Aspiration Hazard: Not an aspiration hazard.

Acute Toxicity Data:

Paraffin Wax: Oral rat LD50 ->5000 mg/kg; Skin rat LD50->5000 mg/kg

Reproductive Toxicity Data: No data available. This product is not expected to cause adverse reproductive effects.

Specific Target Organ Toxicity Single Exposure (STOT-SE):

No data available.

Specific Target Organ Toxicity Repeated Exposure (STOT-RE):

No data available.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

No Eco toxicity data available

- **12.2 Persistence and Degradability:** Wax: Expected to be inherently biodegradable.
- **12.3 Bio-accumulative Potential:** Wax: Has the potential to bioaccumulate; however metabolism or physical properties may reduce the bio concentration or limit bioavailability.
- **12.4 Mobility in Soil:** Wax: Low solubility and floats and is expected to migrate from water to the land. Expected to partition to sediment and wastewater solids.
- 12.5 Results of PBT and vPvB Assessment: Not applicable
- 12.6 Other Adverse Effects: None

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Waste Treatment Recommendations: Dispose in accordance with national and local regulations.

14. TRANSPORT INFORMATION

| | 14.1 UN Number | 14.2 UN Proper Shipping Name | 14.3 Hazard Class(s) | 14.4 Packing Group | 14.5 Environmental Hazards |
|-----------|-------------------|---------------------------------|----------------------------|-----------------------|-------------------------------|
| DOT | None | Not Regulated | None | None | Not applicable |
| ADR/RID | None | Not Regulated | None | None | Not applicable |
| IMDG | None | Not Regulated | None | None | Not applicable |
| IATA/ICAO | None | Not Regulated | None | None | Not applicable |

14.6 Special Precautions for User: Not applicable.

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product is not subject to

CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

Toxic Substances Control Act (TSCA): This product is a medical device and not subject to chemical notification requirements.

Clean Water Act (CWA): This material is not regulated under the Clean Water Act.

Clean Air Act (CAA): This material is not regulated under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories: Not hazardous.

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372): None.

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity: None known.

International Regulations

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

European Inventory of Existing Chemicals (EINECS): This product is a medical device and not subject to chemical notification requirements.

EU REACH: This product is a medical device and not subject to chemical notification requirements.

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 0 Flammability – 1 Physical Hazard – 0

Full text of Classification abbreviations used in Section 2 and 3:

None

Supersedes: 14 February 2014

Date Updated: 27 March 2017

Revision Summary: 3 Year update. Changes to Sections 1, 8, & 11.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website,

Country websites for occupational exposure limits.