

DENTSPLY International
DENTSPLY PROSTHETICS

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 15 January 1986
Document Number: 358
Date Revised: 31 March 2015
Revision Number: 9

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

1.1 Product Identifier:

| | |
|---------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Trade Name (as labeled): | Trubyte® Plastic Teeth |
| Part/Item Number: | 01109, 01111, 01215, 15116, 15120, 15130, 15135, 15140, 15416, 15436, 15446, 15456, 16026, 16036, 16046, 16056, 16066, 16076, 16086, 16096, 16116, 16126, 16136, 16146, 16156, 16166, 16176, 16346, 16356, 16366, 16476, 16566, 16576, 16616, 16626, 16636, 16646, 16656, 16666, 16676, 16686, 16696, 16716, 16726, 16736, 16746, 16756, 16766, 16916, 16936, 16946, 16966, 16976, 16986, 16996, 19656, 21116, 21166, 21146, 21176, 21136, 21126, 21156, 31693, 21626, 21636, 21766, 31691, 21667, 21616, 21686, 21696, 21646, 21346, 21356, 21366, 21476, 21676, 21576, 21656 |

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

| | |
|-----------------------------|-----------------------------------|
| Recommended Use: | Plastic Teeth for Dentures |
| Restrictions on Use: | For Professional Use Only |

1.3 Details of the Supplier of the Safety Data Sheet:

| | |
|------------------------------------------------|-------------------------------------------------|
| Manufacturer/Supplier Name: | DENTSPLY Prosthetics |
| Manufacturer/Supplier Address: | 570 West College Ave. York, PA 17401 |
| Manufacturer/Supplier Telephone Number: | 717-845-7511 (Product Information) |
| Email address: | Prosthetics_MSDS@Dentsply.com |

1.4 Emergency Telephone Number:

| | |
|--------------------------------------------|------------------------------|
| Emergency Contact Telephone Number: | 800-424-9300 Chemtrec |
|--------------------------------------------|------------------------------|

2. HAZARDS IDENTIFICATION

These products are classified as Articles under REACH and National Hazard Communication Regulations and are not subject to the requirements for Information in the Supply Chain (Safety Data Sheets and Labels).

2.1 Classification of the Substance or Mixture:

GHS Classification:

| Health | Environmental | Physical |
|---------------|---------------|---------------|
| Not Hazardous | Not Hazardous | Not Hazardous |

EU Classification: Not Classified.

2.2 Label Elements:

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 # | Classification | WT % |
|------------------------|------------|-----------|----------------|------|
| Non-Hazardous Polymers | Mixture | Mixture | Not Applicable | >99 |
| Titanium Dioxide* | 13463-67-7 | 236-675-5 | Carc. 2, H351 | <0.2 |

*Titanium dioxide is inextricably bound within the polymer matrix of this product.

The exact concentration is being withheld as a trade secret.

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

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:

| | |
|-------------------|-----------------------------------------------------|
| Eye | Flush victim's eyes with water. |
| Skin | Wash skin with soap and water. |
| Inhalation | If irritation develops, remove victim to fresh air. |
| Ingestion | No adverse effects expected. |

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

This product is a non-hazardous polymer solid. Dust generated from polishing or grinding may cause eye or respiratory tract irritation.

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

Immediate medical attention is not required.





Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.

5. FIRE-FIGHTING MEASURES

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| 5.1 Extinguishing Media: | These products are not classified as flammable or combustible but will burn under fire |
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| | conditions. Use media appropriate for surrounding fire. |
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| 5.2 Special Hazards Arising from the Substance or Mixture: |
| Combustion products are toxic. Decomposition may release oxides of carbon, methyl methacrylate, and irritating smoke and fumes. |

| | | | |
|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| 5.3 Advice for Fire-Fighters: | | | |
| Fire Fighting Procedures: | No special precautions required. Fight fire from a safe distance or protected location. | | |
| Precautions for Fire Fighters: | Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection. | | |
| Recommended Protective Equipment for Fire Fighters: | | | |
| EYES/FACE | HANDS | RESPIRATORY | THERMAL |
|  |  |  |  |

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| 6. ACCIDENTAL RELEASE MEASURES |
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| | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|--------------------|-------------|
| 6.1 Personal Precautions, Protective Equipment and Emergency Procedures: | | | |
| If dust from grinding or polishing product is spilled, wear appropriate protective clothing as described in Section 8. Avoid contact with eyes. Avoid breathing dust. | | | |
| Recommended Personal Protective Equipment for Containment and Clean-up: | | | |
| EYES/FACE | HANDS | RESPIRATORY | SKIN |
| | | | |

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| 6.2 Environmental Precautions: |
| Report releases as required by local and national authorities. |

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| 6.3 Methods and Material for Containment and Cleaning up: |
| Pick up teeth and return to container for use. For dust from grinding or polishing products: Contain spills, sweep or gather spilled material in a manner that minimizes the generation of airborne dusts, and transfer to a suitable container for disposal. |

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| 6.4 Reference to Other Sections: |
| Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information. |

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| 7. HANDLING AND STORAGE |
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7.1 Precautions for Safe Handling:

Avoid generating dust. Avoid breathing dust. Use adequate ventilation for polishing or grinding operations. Wash hands thoroughly after polishing or grinding teeth. Use good housekeeping to minimize accumulation of dust.

7.2 Conditions for Safe Storage, Including Any Incompatibilities: No special storage required.

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:**Occupational Exposure Limits:**

| | | |
|------------------------|----------------|--------------------------------------------------------------------------------------|
| Non-Hazardous Polymers | United States | None Established |
| | Germany | None Established |
| | United Kingdom | None Established |
| | European Union | None Established |
| Titanium Dioxide | United States | 10 mg/m ³ TWA ACGIH TLV 15 mg/m ³ TWA OSHA PEL (Total Dust) |
| | Germany | None Established |
| | United Kingdom | 10 mg/m ³ (Inhalable), 4 mg/m ³ (Respirable) TWA UK WEL |
| | European Union | None Established |

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits.

Individual Protection Measures (PPE):

Specific Eye/face Protection: Follow facility requirements for operation.

Specific Skin Protection: None required during the normal use of this product.

Specific Respiratory Protection: None should be needed during normal conditions. If processing generates dust and ventilation is inadequate, use an approved particulate respirator. Respirator selection and use should be based on contaminant type, form and concentration. Use in accordance with applicable regulations and good Industrial Hygiene practice.

Specific Thermal Hazards: None required.

Recommended Personal Protective Equipment

| EYES/FACE | HANDS | RESPIRATORY | SKIN |
|-----------|-------|-------------|------|
| | | | |

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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

| | | | |
|-------------------------------------------------|---------------------|------------------------------------------------|----------------------------------------------------------|
| Appearance: | White plastic solid | Explosive limits: | LEL: Not determined UEL: Not determined |
| Odor: | Not applicable | Vapor pressure (mmHg): | Not applicable |
| Odor threshold: | Not applicable | Vapor density: | Not applicable |
| pH: | Not applicable | Relative density: | Not applicable |
| Melting/freezing point: | Not applicable | Solubility(ies): | Not applicable |
| Initial boiling point and boiling range: | Not available | Partition coefficient: n-octanol/water: | Not applicable |
| Flash point: | Not applicable | Auto-ignition temperature: | Not determined |
| Evaporation rate: | Not applicable | Decomposition temperature: | Not determined |
| 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: Hazardous polymerization will not occur.

10.3 Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

10.4 Conditions to Avoid: None known

10.5 Incompatible materials: Oxidizing agents, reducing agents, acids, and bases.

10.6 Hazardous Decomposition Products: Decomposition may release oxides of carbon, methyl methacrylate, and irritating smoke and fumes.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: No adverse effects expected. Dust may cause eye irritation if teeth are grinded or polished.

Skin: No adverse effects expected.

Ingestion: No adverse effects expected.

Inhalation: No adverse effects expected. Dust may cause respiratory irritation if teeth are grinded or polished.

Chronic Health Effects: None expected.

Irritation: No data available.

Corrosivity: No data available.

Sensitisation: No data available.

Carcinogenicity: This product contains a small amount of titanium dioxide, which is listed by IARC as a suspected carcinogen (Group 2B). Titanium dioxide only presents a risk of cancer by inhalation of very fine dust. None of the other components are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU Directive.

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

Medical Conditions Aggravated by Exposure:

None known.

Acute Toxicity Data:

Non-Hazardous Polymer: No toxicity data available

Titanium dioxide: Oral rat LD50 - >20000 mg/kg; Skin hamster LD50 - >10000 mg/kg

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

Specific Target Organ Toxicity (STOT):

Single Exposure: No data available.

Repeated Exposure: No data available.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

No data available

12.2 Persistence and Degradability: No data available

12.3 Bio-accumulative Potential: No data available

12.4 Mobility in Soil: No data available

12.5 Results of PBT and vPvB Assessment: Not required

12.6 Other Adverse Effects: No adverse effects are expected

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with all national and local regulations.

Properties (Physical/Chemical) Affecting Disposal: Follow all SDS precautions when handling empty containers.

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:

| | | | |
|--------------------------|----|---------------------------|----|
| Immediate Hazard: | No | Pressure Hazard: | No |
| Delayed Hazard: | No | Reactivity Hazard: | No |
| Fire Hazard: | No | | |

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

| Components | C.A.S. # | WT % |
|------------|----------|------|
| None | | |

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity:

| Components | C.A.S. # | WT % |
|------------------|------------|--------|
| Titanium Dioxide | 13463-67-7 | <0.2%* |

*Note: The Titanium Dioxide in this product is in a polymer solid. Regulation applies when titanium dioxide is airborne and in unbound particles of respirable size.

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not subject to WHMIS.

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

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

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

EU REACH: All components requiring registration have been pre-registered.

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.

Korean Existing Chemicals List: 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.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 0 Flammability – 0 Physical Hazard – 0

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

Carc. 2 Carcinogen Category 2

H351 Suspected of causing cancer.

Supersedes: 7 January 2014

Revision Summary: Added new products.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.