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)

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

1.1 Product Identifier:

Trade Name (as labeled): **Trubase® Baseplates**

Part/Item Number: **872970101, 872970102, 870970201, 870970202**

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

Recommended Use: **Resin used in removable dental appliances**

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

2.1 Classification of the Substance or Mixture:

GHS Classification:

Health	Environmental	Physical
Not Hazardous	Not Hazardous	Not Hazardous

EU Classification: Not classified as dangerous

OSHA Specific Hazards: Combustible Dust

2.2 Label Elements:

Signal Word: Warning

Hazard Phrases	Precautionary Phrases
May form combustible dust concentrations in air.	Keep away from all ignition sources including heat,

	sparks, and flame.

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Non-Hazardous Ingredients	Mixture	Mixture	Not applicable	45-55
Mica	12001-26-2	Not applicable	Not applicable	30-40
Titanium Dioxide*	13463-67-7	236-675-5	Carc. 2, H351	5-10
Crystalline Silica as Quartz*	14808-60-7	238-878-4	Xn 48/20 STOT RE 1, H372 Carc 1, H350	<1

*Titanium dioxide and Quartz are inextricably bound within the solid 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	If particles enter eyes, do not rub your eyes. Dust particles may cause abrasive eye injury. Wash eyes with water, while holding the eyelids apart. Get medical attention if irritation persists.
Skin	No first aid should be required. Wash skin with soap and water. Remove and launder clothing before re-use.
Inhalation	No first aid should be required. If dust is inhaled and irritation develops, remove victim to fresh air. Get medical attention if you feel unwell.
Ingestion	Not an anticipated route of exposure. If ingestion occurs and you feel unwell, seek medical advice.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:
Dust generated through grinding may cause eye or respiratory tract irritation. This product contains titanium dioxide and crystalline silica which may cause cancer. The hazardous ingredients in this product are encapsulated into the solid matrix and no exposure is expected in the normal use of this product.

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

5.1 Extinguishing Media:	These products are not classified as flammable or combustible in their solid state, but may burn under fire conditions. Use media appropriate for surrounding fire. Do not use a water stream. Water stream can disperse dust in air producing a fire hazard and possible

	explosion hazard if exposed to ignition source.

5.2 Special Hazards Arising from the Substance or Mixture:
Dust generated in processing of this material may present a potential fire and explosion hazard if suspended in air at high concentrations. Settled dust presents a fire hazard. Re-suspension of the dust into the air by vibration, traffic, material handling, etc. in high concentrations in the presence of an ignition source could result in a dust explosion. Minimize the generation and accumulation of dust. Thermal decomposition may release carbon oxides and irritating fumes.

5.3 Advice for Fire-Fighters:	
Fire Fighting Procedures:	Cool fire exposed containers and structures with water. Do not use solid water jet as that may create a dust cloud that can present an explosion hazard.
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**
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:
Evacuate spill area and keep unprotected personnel away. Eliminate all sources of ignition. Avoid contact with eyes and skin. Avoid breathing dust. If dust from grinding or polishing product is spilled, wear appropriate protective clothing as described in Section 8. Powders that become wet may cause surfaces to be extremely slippery and present a slip hazard.

Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	**HANDS**	**RESPIRATORY**	**SKIN**

6.2 Environmental Precautions:
Report releases as required by local, state, and national authorities
6.3 Methods and Material for Containment and Cleaning up:
For solid product, pick up and return to container for use or disposal. If dust from grinding or polishing is spilled, eliminate all sources of ignition. Scoop or shovel up using methods that minimize the generation of airborne dust. Non-sparking tools should be used. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentrations. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Place dry material into an appropriate container for disposal. Flush spill area with water to remove residue.
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 the eyes and clothing. Avoid breathing dust. Wear protective clothing and equipment as described in Section 8. Use with adequate ventilation. Wash thoroughly with soap and water after handling. Minimize the generation and accumulation of dust. Keep dust away from open flames, hot surfaces and sources of ignition. Silica dust may be in the air without a visible dust cloud. Follow good housekeeping practices to keep surfaces, including areas overhead such as piping, drop ceilings, ductwork, etc. free from settled dust. Dry powders can build static electricity charges when subjected to friction of transfer and in mixing operations. Provide adequate precautions, such as electrical grounding and bonding.

Do not reuse containers. Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers.

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 Ingredients	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Mica	United States	3 mg/m^3 TWA ACGIH TLV (respirable fraction) 20 mppcf TWA OSHA PEL
	Germany	None Established
	United Kingdom	0.8 mg/m^3 TWA (respirable), 10 mg/m^3 TWA (total inhalable) UK OEL
	European Union	Belgium: 3 mg/m^3 TWA
Titanium Dioxide	United States	15 mg/m^3 TWA OSHA PEL (total dust) 10 mg/m^3 TWA ACGIH TLV (respirable fraction)
	Germany	None Established
	United Kingdom	10 mg/m^3 (inhalable); 4 mg/m^3 (respirable dust) TWA UK OEL
	European Union	None Established

Crystalline Silica as Quartz	United States	$\frac{10 \text{ mg/m}^3}{\% \text{ SiO}_2 + 2}$ TWA OSHA PEL (respirable fraction) $\frac{30 \text{ mg/m}^3}{\% \text{ SiO}_2 + 2}$ TWA OSHA PEL (Total dust) 0.025 mg/m^3 TWA ACGIH TLV (respirable)
	Germany	None Established
	United Kingdom	0.1 mg/m^3 TWA UK WEL (as Silica, respirable crystalline)
	European Union	Belgium: 0.1 mg/m^3 TWA

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: Use adequate general or local exhaust ventilation to maintain exposures below the occupational exposure limits. Provide local exhaust ventilation where product is processed in a manner that generates dust. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling this product contain explosion relief vents or an explosion suppression system or an oxygen deficient environment. Ensure that dust handling systems (such as exhaust ducts, dust collectors, vessels and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e. there is no leakage from the equipment). Use only appropriately classified electrical equipment.

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 for normal use. If the exposure limits are exceeded, an approved respirator with dust/mist cartridges or supplied air respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice.
Specific Thermal Hazards: None required.

Recommended Personal Protective Equipment			
EYES/FACE	**HANDS**	**RESPIRATORY**	**SKIN**

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Pinkish brown solid in sheet form.	**Explosive limits:**	**LEL:** Not determined **UEL:** Not determined
Odor:	No odor.	**Vapor pressure (mmHg):**	Not applicable
Odor threshold:	Not available	**Vapor density:**	Not applicable
pH:	Not applicable	**Relative density:**	1.93
Melting/freezing point:	>120°C (248°F)	**Solubility(ies):**	Very slightly soluble

Initial boiling point and boiling range:	Not available	**Partition coefficient: n-octanol/water:**	Not applicable
Flash point:	Not applicable	**Auto-ignition temperature:**	Not available
Evaporation rate:	Not applicable	**Decomposition temperature:**	Not available
Flammability (solid, gas):	May form combustible dust concentrations in air	**Viscosity:**	Not applicable
Explosive Properties:	High concentrations of dust from grinding may present a fire or explosion hazard.	**Oxidizing Properties:**	None

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Non-reactive

10.2 Chemical Stability: Stable under normal handling and storage conditions.

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

10.4 Conditions to Avoid: Avoid heat, sparks, flames and all other sources of ignition. Avoid hygroscopic conditions and dust formation.

10.5 Incompatible materials: Avoid oxidizing agents, strong bases, and reducing agents.

10.6 Hazardous Decomposition Products: Thermal decomposition may release carbon oxides and irritating fumes.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:
Eyes: Dust generated during grinding may cause eye irritation.
Skin: Dust may cause mechanical irritation.
Ingestion: No adverse effects expected. Ingestion of large amounts of dust may cause gastrointestinal irritation.
Inhalation: No adverse effects expected. Dust may cause irritation if plates are ground or polished.

Chronic Health Effects: None expected.

Irritation: This product is not expected to cause eye or skin or eye irritation. Mechanical irritation may occur.

Corrosivity: No data available.

Sensitisation: No data available.

Carcinogenicity: Titanium dioxide is listed by IARC as a group 2B carcinogen (possible human carcinogen). Crystalline silica quartz is listed as “Carcinogenic to Humans” (Group 1) by IARC and “Known to be a Human Carcinogen" by NTP. None of the other components of this product are listed as carcinogens by OSHA, IARC or NTP or the EU CLP.

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 Ingredients: No data available.
Mica: No data available
Titanium Dioxide: Oral rat LD50 - >20000 mg/kg; Skin hamster LD50 - >10000 mg/kg
Crystalline Silica: Oral Rat LD50 - >10,000 mg/kg; Inhalation rat LC50 - >0.139 mg/l/4hr; Dermal rabbit LD50- >5000 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:
Crystalline Silica Quartz: 72 hr LC50 Carp - >10,000 mg/L

This product is not expected to present an environmental hazard.

12.2 Persistence and Degradability: Biodegradation is not applicable to inorganic substances.

12.3 Bio-accumulative Potential: This product is not expected to be bio-accumulative in aquatic organisms.

12.4 Mobility in Soil: No data available

12.5 Results of PBT and vPvB Assessment: No data available

12.6 Other Adverse Effects: No data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

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

Properties (Physical/Chemical) Affecting Disposal: Empty containers retain product residues and can be hazardous. 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:	Yes		

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 %
Crystalline Silica as Quartz	14808-60-7	<1%
Titanium Dioxide	13463-67-7	5-10%

Note: Titanium dioxide and Quartz are inextricably bound within the solid matrix of this product.

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: 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.

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 – 1 Flammability – 2 Physical Hazard– 0

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

Xn Harmful
R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation
Carc. 1A Carcinogen Category 1A
Carc. 2 Carcinogen Category 2
STOT RE 1 Single Target Organ Toxicity Repeated Exposure 1
H350 May cause cancer
H351 Suspected of causing cancer.
H372 Causes damage to organs through prolonged exposure

Supersedes: 30 September 2011
Date updated: 6 February 2015
Revision Summary: Converted MSDS to Reach SDS. Updated all sections.

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