



MATERIAL SAFETY DATA SHEET

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/PREPERATION AND OF THE COMPANY/UNDERTAKING

Product Name: Ceramco® iC Dentin, High Chroma Modifier, Opaceous Dentin, Natural Enamel, Opal Enamel, Mamelon, Margin, Final Margin, Add-On, Powder Opaque, Powder Opaque Modifier, Opaque Corrector, Paste Opaque Crystals, Stains, Overglaze

Product Number: Dentin: 4450301-4450346, 4450501-4450546; High Chroma Modifier: 4500301-4450313; Opaceous Dentin: 4400301-4400346, 4400501-4400546; Natural Enamel: 4600301-4600325, 4600501-4600521; Opal Enamel: 4650315-4650320, 4650515-4650520; Mamelon: 4550301-4550302; Margin (PFM): 4700301-4700316, Margin (PTM): 4860301-4860310; Final Margin: 4702301-4702308; Add-On: 4750300-4750326, 4760301-4760304; Powder Opaque: 4100401-4100447; Powder Opaque Modifier: 4150301-4150306; Opaque Corrector: 4350301—4350309; Paste Opaque Crystals: 4300207; Stains: 4740101-4740117; Overglaze 4050210

MSDS Code Number: 301

Manufacturer: Dentsply Prosthetics
Address: 570 West College Ave.
York, PA 17405-0872
Information Telephone Number: 717-845-7511
Emergency Telephone Number: 800-424-9300 Chemtrec
Email: Prosthetics_MSDS@Dentsply.com

Product Use: Used in fabrication of dental crown, bridges, and laminated veneers

Date of Last Revision: New, November 15, 2009

SECTION 2 HAZARDS IDENTIFICATION

Emergency Overview: May cause eye irritation. Dust from grinding or polishing may cause mechanical eye and upper respiratory tract irritation.

EU Preparation Classification (1999/45/EC): Not classified as a dangerous preparation

SECTION 3 COMPOSITION INFORMATION ON INGREDIENTS

Ingredient	CAS No./EINECS No.	Percent	EC Substance Classification (67/548/EEC)
Sodium Potassium Aluminosilicate	Proprietary	80-100	Not Applicable
Tin Oxide	21651-19-4	0-5	Not Applicable

See Section 16 for further information on EU Classification.

SECTION 4 FIRST AID MEASURES

Eye Contact: Flush eyes with water for at least 15 minutes, holding the eyelids apart. Check victim for contact lenses and remove if possible while flushing. Get medical attention if irritation persists.

Skin Contact: Wash with soap and water.

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 irritation or discomfort occurs, get medical attention.

Inhalation: Remove victim to fresh air. Get medical attention if irritation develops.

SECTION 5 FIRE FIGHTING PROCEDURES

Extinguishing Media: This product is not combustible. Use any extinguishing media that is suitable for the surrounding fire.

Firefighting Procedures: Firefighters should wear full emergency equipment and NIOSH approved positive pressure self-contained breathing apparatus in fires involving chemicals.

Unusual Fire/Explosion Hazards: None known.

Known or Anticipated Hazardous Products of Combustion: None known.

SECTION 6 ACCIDENTAL RELEASE MEASURES

Accidental Release Measures Wear appropriate protective clothing as described in Section 8. Promptly clean up spills by sweeping or scooping into appropriate containers for disposal.

Personal Precautions: Avoid contact with eyes. Do not breathe dust.

Environmental Precautions: No special measure required.

SECTION 7 HANDLING AND STORAGE

Handling: Avoid contact with eyes. Use with adequate ventilation. Wash hands thoroughly after handling.

Storage: Store in a cool, dry location to prolong shelf life, if any. Protect from physical damage.

SECTION 8 EXPOSURE CONTROLE/PERSONAL PROTECTION

Occupational Exposure Limits:

Sodium Potassium Aluminosilicate	None Established
Tin oxide	None Established

Engineering Controls: When grinding or polishing, use with adequate general or local exhaust ventilation to minimize exposure levels.

Personal Protective Equipment

Eye Protection: Safety glasses are recommended when handling or when grinding or polishing.

Skin Protection: Wear impervious gloves to protect hands when grinding or polishing.

Respiratory Protection: When grinding, polishing or where exposure levels are excessive, a NIOSH 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 OSHA 1910.134 and good Industrial hygiene practice.

Other Protective Clothing or Equipment: Suitable washing and eye flushing facilities must be available in the work area. When grinding or polishing, wear impervious clothing as needed to avoid contamination of personal clothing.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor: Solid powder in various colors without an odor.

Boiling Point: Not applicable

Freezing Point: Not applicable

Solubility in Water: Insoluble in water (<0.1%)

Vapor Pressure (mmHg): Not applicable

Evaporation Rate: Not applicable

% Volatile by Volume: Negligible

Flammable Limits in Air:

LEL: Not applicable

UEL: Not applicable

Melting Point: Not applicable

Specific Gravity: 2.4 - 3.1 gm/cc @ 20°C

pH: Not applicable

Vapor Density: Not applicable

Viscosity: Not applicable

Flashpoint: Not applicable

Autoignition Temperature: Not applicable

SECTION 10 STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: No known dangerous reactions.

Incompatibility with Other Materials: No known incompatible materials.

Hazardous Decomposition Products: No known decomposition products.

SECTION 11 TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eyes: Direct contact with powder may cause irritation with redness, burning and tearing. Dust from grinding or polishing may cause mechanical irritation.

Skin: This product does not irritate skin. Non-sensitizing in Kligman Maximization Test.

Ingestion: No adverse effects are expected from swallowing small amounts. This product was found to be non-toxic which was tested with laboratory animals. This product was found to be non-irritating to mucous membranes in studies with laboratory animals.

Inhalation: Not expected to cause respiratory tract irritation. Dust from grinding or polishing may cause sneezing, coughing, and other signs of mechanical irritation.

Chronic Health Effects: Not known.

Carcinogenicity: None of the components are listed as possible carcinogens by NTP, IARC, ACGIH, the EU Dangerous Substances Directive, or OSHA.

Medical Conditions Aggravated by Exposure: Pre-existing respiratory diseases and eye conditions such as dermatitis may be aggravated by exposure to this material.

Mutagenicity: This product tested negative in the Ames Test for Mutagenicity.

Acute Toxicity Data:

Sodium Potassium Aluminosilicate No data available

Tin Oxide No data available

SECTION 12 ECOLOGICAL INFORMATION

Sodium Potassium Aluminosilicate No data available

Tin Oxide No data available

SECTION 13 DISPOSAL CONSIDERATIONS

Dispose in accordance with local, state, and federal regulations for disposal of solid waste.

SECTION 14 TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated
DOT Hazard Class: N/A
UN Number: N/A
DOT Labels Required (49CFR172.101): N/A

IATA Shipping Name: Not Regulated
IATA Hazard Class: N/A
UN Number: N/A
IATA Labels Required (49CFR172.101): N/A

IMDG Shipping Name: Not Regulated
IMDG Class: N/A
UN Number: N/A
IMSG Labels: N/A

SECTION 15 REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS:

CERCLA: This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report all spills in accordance with federal, state and local regulations.

SARA TITLE III:
Hazard Category For Section 311/312: Non-hazardous.

Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None.

Section 302 Extremely Hazardous Substances (TPQ): None.

EPA Toxic Substances Control Act (TSCA) Status: All of the components of this product are listed on TSCA inventory.

U.S. STATE REGULATIONS

California Proposition 65: This product does not contain substance that is known to the State of California to cause cancer.

INTERNATIONAL REGULATIONS:

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

Canadian WHMIS Classification: Medical devices are not subject to WHMIS.

European Community Labeling: Not a dangerous preparation.

European Inventory of New and Existing Chemicals Substances (EINECS): 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.

SECTION 16 OTHER INFORMATION

NFPA Hazard Rating:

Health – 1 Flammability – 0 Reactivity – 0

EU Classes and Risk Phrases for Reference (See Sections 2 and 3): None.

New: 11/15/2009