

DENTSPLY International
DENTSPLY PROSTHETICS

Safety Data Sheet

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

Date Issued: 06 June 2013
Document Number: 452
Date Revised: 23 February 2016
Revision Number: 2

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

1.1 Product Identifier:

Trade Name (as labeled):

CELTRA® Overglaze and Stains

Part/Item Number:

Overglaze: 601322; Stain: 601500-601505, 601511, 601512, 601520-601526

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

Recommended Use:

Used for staining and glazing CELTRA DUO and other lithium silicate based restorations and Cercon zirconia.

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

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 %
Amorphous Silica, Fused*	60676-86-0	262-373-8 /	Not applicable	50-60
1, 3 Butylene Glycol	107-88-0	203-529-7 /	Not applicable	0-18
Di(propylene) Glycol	25265-71-8	246-770-3 /	Not applicable	0-12
Aluminum Oxide*	1344-28-1	215-691-6 /	Not applicable	<10
Sodium Oxide*	1313-59-3	215-208-9 /	Skin Corr. 1B, H314	<10
Potassium superoxide*	12030-88-5	234-746-5 /	Oxid. Sol. 1, H271 Skin Corr. 1A, H314 EUH014	<10
Barium Oxide*	1304-28-5	215-127-9 /	Oxid. Sol. 1, H271 Acute Tox. 3, H301 Eye Dam. 1, H318 Skin Corr. 1B, H314	<10
Boron Trioxide*	1303-86-2	215-125-8 /	Repro 1B, H360	<10
Lithium oxide*	12057-24-8	235-019-5 /	Eye Dam. 1, H318 Skin Corr. 1B, H314	<5
Tin Dioxide*	18282-10-5	242-159-0 /	Not applicable	<5
Magnesium Oxide*	1309-48-4	215-171-9 /	Not applicable	<5
Zinc Oxide*	1314-13-2	215-222-5 /	Aquatic Acute 1, H400 Aquatic Chronic 1, H410	<5
Calcium Oxide*	1305-78-8	215-138-9 /	Eye Dam. 1, H318 Skin Irrit. 2, H315 STOT SE 3, H335	<3
Antimony Trioxide*	1309-64-4	215-175-0 /	Carc. 2, H351	<1
Titanium Dioxide*	13463-67-7	236-675-5 /	Carc. 2, H351	<1

*Note: These components are inextricably bound together within the glass matrix of this product. The material produced during the handling of this product is not hazardous.

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 Description of First Aid Measures:

Eye	Flush victim's eyes with water, while holding the eyelids apart. Check victim for contact lenses and remove if possible while flushing. Get medical attention if irritation occurs and persists.
Skin	Wash skin with soap and water.
Inhalation	Remove victim to fresh air. If irritation or other symptoms persist, get medical attention.
Ingestion	If small quantities are swallowed, rinse out mouth with water. Do not induce vomiting. If irritation or discomfort occurs, get medical attention.

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

Direct contact with dust from dried paste may cause eye irritation. Inhalation of dust or vapors from staining and glazing procedures may cause nose and throat irritation and nervous system effects. Ingestion may cause abdominal discomfort or pain, nausea, vomiting, dizziness, drowsiness, and other central nervous system effects.

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

Immediate medical attention should not be required.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Use media appropriate for surrounding fire.
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5.2 Special Hazards Arising from the Substance or Mixture:

Decomposition may release oxides of carbon and butadiene.

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures/Precautions for Fire Fighters:	Use water to cool fire-exposed containers. Fight fire from a safe distance or protected location. Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection.
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6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Avoid prolonged contact with skin, eyes or clothing. Avoid breathing dust from dried paste or vapors. Ventilate area. Wear appropriate protective clothing as described in Section 8.

6.2 Environmental Precautions:

Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Promptly wipe up or scoop up spills and place in appropriate containers for disposal. Clean spill area with water.

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 Handling:

Avoid prolonged contact with the eyes, skin and clothing. Avoid breathing dust from dried paste or vapors. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.

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:

Store in a cool, dry, well-ventilated area away from incompatible materials. Keep containers closed when not in use.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

Amorphous Silica, Fused	10 mg/m ³ TWA OSHA PEL (respirable fraction) % SiO ₂ + 2
	30 mg/m ³ TWA OSHA PEL (Total dust) % SiO ₂ + 2
	0.3 mg/m ³ TWA DFG MAK (Respirable)
	0.08 mg/m ³ TWA UK WEL
	0.1 mg/m ³ TWA Belgium OEL
1, 3 Butylene Glycol	None Established
Di(propylene) Glycol	100 mg/m ³ TWA, 200 mg/m ³ STEL DFG MAK (Skin) (Inhalable, sum of vapor and aerosol)
Aluminum Oxide	5 mg/m ³ (respirable fraction), 15 mg/m ³ (total dust) TWA OSHA PEL 1 mg/m ³ TWA ACGIH TLV (Respirable) (as Aluminum, metal and insoluble compounds)
	4 mg/m ³ TWA DFG MAK (Inhalable)
	1.5 mg/m ³ TWA DFG MAK (Respirable)
	10 mg/m ³ (Inhalable) TWA UK WEL 4 mg/m ³ (Respirable) TWA UK WEL

Sodium Oxide	None Established
Potassium superoxide	None Established
Barium Oxide	None Established
Boron Trioxide	10 mg/m ³ ACGIH TLV 15 mg/m ³ OSHA PEL (total dust) ³ 10 mg/m ³ TWA, 20 mg/m ³ STEL UK WEL 10 mg/m ³ TWA Belgium OEL
Lithium oxide	1 mg/m ³ Ceiling AIHA WEEL
Tin Dioxide	2 mg/m ³ TWA ACGIH TLV (as Tin Oxides, as Sn)
	2 mg/m ³ TWA EU OEL (as Tin compounds, inorganic, except SnH ₄)
	2 mg/m ³ TWA, 4 mg/m ³ STEL UK WEL (as Tin compounds, inorganic, except SnH ₄)
Magnesium Oxide	10 mg/m ³ TWA ACGIH TLV (Inhalable) 15 mg/m ³ TWA OSHA PEL (as fume) (total particulate)
	1.5 mg/m ³ TWA DFG MAK (respirable) 4 mg/m ³ TWA DFG MAK (inhalable)
	10 mg/m ³ TWA UK WEL (inhalable) 4 mg/m ³ TWA UK WEL (respirable)
	10 mg/m ³ TWA Belgium OEL
Zinc Oxide	2 mg/m ³ TWA, 10 mg/m ³ STEL ACGIH TLV (Respirable) 5 mg/m ³ (respirable fraction), 15 mg/m ³ (total dust) TWA OSHA PEL
	0.1 mg/m ³ TWA, 0.4 mg/m ³ STEL (Respirable) DFG MAK 2 mg/m ³ TWA, 4 mg/m ³ STEL (inhalable) DFG MAK
	5 mg/m ³ TWA, 10 mg/m ³ STEL UK WEL (as fume or respirable dust)
	10 mg/m ³ TWA Belgium OEL (as dust) 5 mg/m ³ TWA, 10 mg/m ³ STEL Belgium OEL (as fume or respirable dust)
Calcium Oxide	2 mg/m ³ TWA ACGIH TLV 5 mg/m ³ TWA OSHA PEL
	1 mg/m ³ TWA, 2 mg/m ³ STEL DFG MAK (Inhalable)
	2 mg/m ³ TWA UK WEL
	2 mg/m ³ TWA Belgium OEL
Antimony trioxide	0.5 mg/m ³ TWA ACGIH TLV 0.5 mg/m ³ TWA OSHA PEL
	0.5 mg/m ³ TWA UK WEL
Titanium Dioxide	10 mg/m ³ TWA ACGIH TLV 15 mg/m ³ TWA (Total dust) OSHA PEL
	10 mg/m ³ (Inhalable) TWA UK WEL 4 mg/m ³ (Respirable) TWA UK WEL
	10 mg/m ³ TWA Belgium OEL
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: Chemical safety glasses are recommended if contact is possible.

Specific Skin Protection: Wear impervious gloves to avoid prolonged skin contact.

Specific Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded an approved dust/mist respirator 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Paste in various colors	Explosive limits:	LEL: Not applicable UEL: Not applicable
Odor:	Odorless	Vapor pressure (mmHg):	Not applicable
Odor threshold:	Not applicable	Vapor density:	Not applicable
pH:	Not applicable	Relative density:	2.4-2.8 gm/cc @ 68°F (20°C)
Melting/freezing point:	Not applicable	Solubility(ies):	Insoluble in water (<0.1%)
Initial boiling point and boiling range:	Not determined	Partition coefficient: n-octanol/water:	Not applicable
Flash point:	Not determined	Auto-ignition temperature:	Not applicable
Evaporation rate:	Not determined	Decomposition temperature:	Not determined
Flammability (solid, gas):	Not flammable	Viscosity:	Not determined
Explosive Properties:	Not explosive	Oxidizing Properties:	None

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.

10.2 Chemical Stability: Stable under normal storage and handling conditions. Product does not degrade and partially evaporates.

10.3 Possibility of Hazardous Reactions: None known.

10.4 Conditions to Avoid: None known.

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

10.6 Hazardous Decomposition Products: When heated to decomposition emits oxides of carbon and butadiene.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Direct contact with the paste may cause irritation with redness, burning and tearing. Dust from dried paste may cause mechanical irritation.

Skin: This product does not irritate skin.

Ingestion: No adverse effects are expected from swallowing small amounts.

Inhalation: Not expected to cause respiratory tract irritation.

Chronic Health Effects: None known.

Irritation: No data available for the mixture. This product may cause mechanical irritation.

Corrosivity: This product is not expected to be corrosive.

Sensitization: No data available for the mixture. Based on the components, this product is not expected to cause skin sensitization.

Carcinogenicity: Titanium dioxide and Antimony trioxide are listed by IARC as Probably Carcinogenic to Humans (group 2B). The components of this product are inextricably bound together during the glass melting/forming process during manufacturing. Therefore, there is no exposure to Titanium dioxide or Antimony trioxide during the normal use and handling. None of the other components of this product are listed as carcinogens by OSHA, IARC, NTP, or the EU CLP.

Mutagenicity: 1, 3 Butylene glycol: Rats were fed butane-1,3-diol in concentrations up to 24% of the diet and paired to produce F1A, F2A and F3A litters. Analysis of the femur bone marrow of at least two animal per sex and dose of these litters revealed no increase in chromosomal aberrations. Not mutagenic in vivo (rat dominant lethal and cytogenetic assays).

Acute Toxicity Data:

Amorphous Silica, Fused: No toxicity data available

1, 3 Butylene Glycol: Oral rat LD50 – 18.6-30 g/kg

Di(propylene) Glycol: Oral rat LD50- >5000 mg/kg; Skin rabbit LD50- >5010 mg/kg

Aluminum Oxide: Oral rat LD50->10000 mg/kg, Inhalation rat LC50- 7.6 mg/L/1hr

Sodium Oxide: No toxicity data available

Potassium superoxide: No toxicity data available

Barium Oxide: No data available.

Boron Trioxide: Oral rat LD50- 3450 mg/kg, Inhalation rat LC50- >2.12 mg/L/4hr (no deaths), Skin rabbit LD50- >2000 mg/kg

Lithium oxide: No toxicity data available

Tin Dioxide: Inhalation rat LC50- >2.04 mg/L/4hr (no deaths)

Magnesium Oxide: Oral rat LD50- 3870 mg/kg

Zinc Oxide: Oral rat LD50:>5000 mg/kg, Inhalation rat LC50: >1.79 mg/L/4 hr (no mortality), Dermal rat LD50: >2000 mg/kg

Calcium Oxide: Oral rat LD50->2000 mg/kg, Skin rabbit LD50->2500 mg/kg

Antimony trioxide: Inhalation rat LC50- >5.2 mg/L/4hr, Skin rabbit LD50- >8300 mg/kg

Titanium Dioxide: Oral rat LD50 >5000 mg/kg, Inhalation rat LC50 >6.82 mg/L/4 hr

Reproductive Toxicity Data: 1, 3 Butylene glycol: In a study of twenty five rats of both sexes were fed either control diet or diet supplemented with 1,3-butylene glycol at dose levels of 5, 10 or 24% of the diet (2500, 5000 or 12000 mg/kg by weight/day). 1,3-butylene glycol did not influence fertility in a five generation study with an embedded continuous breeding study in concentrations up to 10% in the diet (5000 mg/kg). In the highest concentration tested (24%, 12000 mg/kg) no offspring in the fifth litter of the F2 generation were produced. Boron Oxide: In a animal study, rats exposed to the high dose of 336 mg/kg by weight boric acid (corresponding to a level of 58.5 mg Boron/kg bw) were sterile. Microscopic examination of the atrophied testes of all males in this group showed no viable sperm. There were also reported evidence of decreased ovulation in about half of the ovaries examined from the females exposed to 58.5 mg Boron/kg bw and only 1/16 matings produced a litter from these high dose females when mated with control male animals. In another animal study, an increased incidence of malformed live fetuses/litter was observed at 43.5 mg Boron/kg by weight, primarily due to cardiovascular defects. Antimony trioxide: Pregnant female rats (six to seven per group) were exposed by inhalation to 0, 0.027, 0.082 or 0.27 mg/m³ antimony trioxide for 24 hours per day for 21 days. Fetal growth and viability were assessed at the end of gestation. Maternal body weight gain was not affected by exposure, but, at the high-dose level, increased pre- and postimplantation death of embryos was observed. At the mid-dose level, preimplantation loss and fetal growth retardation were evident. The Boron oxide in this product is bound in a glass matrix, exposure to Boron Oxide is unlikely.

Specific Target Organ Toxicity Single Exposure (STOT-SE): No data available

Specific Target Organ Toxicity Repeated Exposure (STOT-RE): 1, 3 Butylene glycol: No treatment related adverse effects were observed in a chronic feeding-study in rats which received up to 10% (5000 mg/kg/d) 1, 3-butylene glycol in food.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

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: 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:

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: Titanium Dioxide <1%, Antimony trioxide <1%

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

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.

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 – 0 Physical Hazard– 0

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

Acute Tox. 3 Acute Toxicity Category 3

Acute Tox. 4 Acute Toxicity Category 4

Aquatic Acute 1 Aquatic Acute Toxicity Category 1

Aquatic Chronic 1 Aquatic Chronic Toxicity Category 1

Carc. 2 Carcinogen Category 2

Eye Dam. 1 Eye Damage Category 1

Oxid. Sol. 1 Oxidizing Solid Category 1

Repro 1B Reproductive Toxicity Category 1B

Skin Corr. 1 Skin Corrosion Category 1

Skin Irrit. 2 Skin Irritant Category 2

STOT RE 2 Specific Target Organ Toxicity Repeated Exposure Category 2

STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3

H271 May cause fire or explosion; strong oxidizer.

H301 Toxic if swallowed.

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H335 May cause respiratory irritation.

H351 Suspected of causing cancer.

H360 May damage fertility or the unborn child.

H373 May cause damage to organs through prolonged or repeated exposure.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

EUH014 Reacts violently with water.

Supersedes: 29 July 2015

Date Updated: 23 February 2016

Revision Summary: Converted MSDS to Reach SDS, Updated all sections.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA Registered Substances, C&L Inventory, Country websites for occupational exposure limits.