

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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Revision Number: 2

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

1.1 Product Identifier:

Trade Name (as labeled):

DENTSPLY Universal Stain & Glaze Liquid
CELTRA® Universal Stain & Glaze Liquid
Ceramco® 3 Stain & Glaze Liquid
Ceramco® PFZ Stain/Glaze Liquid

Part/Item Number:

601315, 601350, 30132, 501325

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

Recommended Use:

**Used to dilute Stain & Glaze Paste or Powder Porcelains
in shading and glazing restorations to improve esthetics.**

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 a dangerous preparation

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 #	Classification	WT %
1,3-Butylene glycol	107-88-0	203-529-7	Not Applicable	≥99

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, while holding the eyelids apart. Get medical attention if irritation develops or persists.
Skin	Flush skin with plenty of water. Get medical attention if irritation develops or persists.
Inhalation	Remove victim to fresh air. Get medical attention if irritation develops.
Ingestion	Do not induce vomiting. Rinse mouth with water. Never give anything by mouth to an unconscious or drowsy person. Get immediate medical attention.

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

May cause eye, skin and respiratory tract irritation.

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

Immediate medical attention is required for ingestion.

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





5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:

Use water spray, dry material, foam or carbon dioxide.

5.2 Special Hazards Arising from the Substance or Mixture:

Closed containers may explode if exposed to extreme heat. May produce combustible vapors if heated. Decomposition may release carbon monoxide and butadiene.

5.3 Advice for Fire-Fighters:			
Fire Fighting Procedures:	Cool exposed intact containers with water spray. Do not direct a solid stream of water or foam into hot, burning pools of liquid. This may cause frothing and increase fire intensity.		
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. Ventilate area. Wear appropriate protective clothing as described in Section 8.			
Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	HANDS	RESPIRATORY	SKIN

6.2 Environmental Precautions:
Prevent entry into sewers and waterways. Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:
Contain and collect using an inert absorbent material and place in appropriate containers for disposal. Clean spill site 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 contact with the eyes, skin and clothing. Wear protective clothing and equipment as described in Section 8. Use 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: This product is hygroscopic. Store only in the original container. Keep container tightly closed. Store in a container in a cool, dry, well-ventilated location away from incompatible materials. Protect from physical damage.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

1,3-Butylene glycol	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established

Biological Exposure Limits: None Established

8.2 Exposure Controls:

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

Individual Protection Measures (PPE):

Specific Eye/face Protection: Chemical safety glasses should be worn to avoid contact.

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

Specific Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded an approved organic vapor 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:	Clear, colorless liquid	Explosive limits:	LEL: 1.9% UEL: 12.6%
Odor:	Odorless	Vapor pressure (mmHg):	0.06 mmHg @ 68°F (20°C)
Odor threshold:	Not available	Vapor density: (Air = 1)	3.1
pH:	Not available	Relative density:	1.006 gm/cc @ 68°F (20°C)
Melting/freezing point:	-107°F (-77°C)	Solubility(ies):	Completely soluble in water
Initial boiling point and boiling range:	405.5°F (207.5°C)	Partition coefficient: n-octanol/water:	Not available
Flash point:	239°F (115°C)	Auto-ignition temperature:	711°F (377°C)
Evaporation rate:	Not available	Decomposition temperature:	Not available
Flammability (solid, gas):	Not applicable	Viscosity:	104 mPa•s
Explosive Properties:	Not available	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 conditions.

10.3 Possibility of Hazardous Reactions: None known.

10.4 Conditions to Avoid: Keep away from heat, sources of ignition, and exposure to moist air or water.

10.5 Incompatible materials: Avoid oxidizing agents, acids, and isocyanates.

10.6 Hazardous Decomposition Products: When heated to decomposition emits toxic carbon monoxide and butadiene.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: May cause mild irritation with redness and tearing.

Skin: May cause slight irritation to skin.

Ingestion: Small amounts may cause gastric upset. Large amounts may cause gastrointestinal discomfort and central nervous effects including dizziness, fatigue and loss of consciousness or in severe causes, death.

Inhalation: No adverse effects expected under normal use. High aerosol concentrations may cause irritation of the nose and throat, and central nervous system effects such as dizziness, fatigue, and loss of consciousness.

<u>Chronic Health Effects:</u> Prolonged or repeated skin contact may cause irritation and defatting of the skin.
<u>Irritation:</u> 1,3-Butylene glycol: Not irritating to rabbit skin and slightly irritating to rabbit eyes.
<u>Corrosivity:</u> This product is not expected to be corrosive.
<u>Sensitization:</u> This product showed no evidence of skin sensitizing.
<u>Carcinogenicity:</u> None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU Directive.
<u>Mutagenicity:</u> 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).
<u>Medical Conditions Aggravated by Exposure:</u> Individuals with pre-existing skin, respiratory, liver and kidney disease may be at increased risk from exposure.
<u>Acute Toxicity Data:</u> 1,3-Butylene glycol: Oral rat LD50 – 18.6-30 g/kg
<u>Reproductive Toxicity Data:</u> 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.
<u>Specific Target Organ Toxicity (STOT):</u> <u>Single Exposure:</u> No data available. <u>Repeated Exposure:</u> 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: 1,3-Butylene glycol: 48hr EC50 Daphnia magna - >1000 mg/L; 72hr ErC50 Algae - >1070 mg/L
12.2 Persistence and Degradability: 1,3-Butylene glycol: Readily biodegradable – 81% after 29 days.
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 applicable
12.6 Other Adverse Effects: None

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): All of the components of this product are listed on the TSCA inventory.

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 %
None		

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Not a controlled product.

Canadian Environmental Protection Act: All of the components in this product are listed on the Domestic Substances list (DSL).

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): All of the components in this product are listed on the EINECS inventory.

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

Australian Inventory of Chemical Substances: All of the components in this product are listed on the AICS for Australia.

China Inventory of Existing Chemicals and Chemical Substances: All of the components in this product are listed on the IECSC for China.

Japanese Existing and New Chemical Substances: All of the components in this product are listed on the Japanese ENCS list.

Korean Existing Chemicals List: All of the components in this product are listed on the KECL for Korea.

Philippine Inventory of Chemicals and Chemical Substances: All of the components in this product are listed on the PICCS.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 1 Flammability – 1 Physical Hazard – 0

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

None

Supersedes: 9 January 2014

Revision Summary: added Ceramco 3 Stain and Glaze Liquid, Ceramco PFZ Stain and Glaze Liquid and DENTSPLY Universal Stain and Glaze Liquid.

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