

SAFETY DATA SHEETS

This SDS packet was issued with item:

072692911

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

070866798 072692705 072692721 072692739 072692747 072692754 072692762 072692770 072692788 072692796
072692804 072692812 072692820 072692838 072692846 072692853 072692861 072692903 072722213 072722221
072722239 072722247 072722254 072722262 072722288 072722296 072722304 072722312 072722320 072722338
072722346 072722353 072722361 072722379 072722387 072722395 072722403 072722411 072722429 072722502
072722569 072722577 072722585 072722593 072722601 072722619 072722627 072722635 072722643 072722700
072722718 072722726 072722759 072722767 072722775 072722783 072722791 072722809 072722817 072722825
072722833 072722841 072722858 072722866 072722874 072722908 072722916 072722924 072722932 072722940
072722957 072722965 072722973 072722981 072722999 072723005 072723013 072723021 072723039 072723047

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: 06 June 2013
Document Number: 452
Date Revised: 11 September 2013
New

1. PRODUCT IDENTIFICATION

Trade Name (as labeled): CELTRA™ Universal Overglaze, Universal Stain

Product Identifier (Part/Item Number): Overglaze: 601322; Stain: 601500-601505, 601511, 601512, 601520-601526

U.N. Number: Not Regulated

U.N. Dangerous Goods Classification: Not Regulated

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

Manufacturer/Supplier Name: Dentsply Prosthetics

Manufacturer/Supplier Address: 570 West College Ave.
York, PA 17405-0872

Manufacturer/Supplier Telephone Number: 717-845-7511 (Product Information)

Emergency Contact Telephone Number: 800-424-9300 Chemtrec

Email address: Prosthetics_MSDS@Dentsply.com

2. HAZARD(s) IDENTIFICATION

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

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

Labeling in accordance with 1999/45/EC

None Required

US Hazard Classification: Not Hazardous

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. #	EINECS #	Substance Classification	WT %
Sodium Potassium Aluminosilicate	Proprietary	Proprietary	Not Applicable	60-70

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





The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS and H phrases and EU Classifications and R Phrases.

4. FIRST-AID MEASURES





Routes of Exposure	First Aid Instructions
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 plenty of water. Get medical attention if irritation develops or persists.
Inhalation	Remove victim to fresh air. Get medical attention if irritation develops.
Ingestion	If small quantities are swallowed, rinse out mouth with water. Do not induce vomiting. If irritation or discomfort occurs, get medical attention.
Most important symptoms of exposure	May cause eye irritation.
Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically. Immediate medical attention should not be required.	

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media:	Use dry chemical, carbon dioxide, alcohol or polymer foam.		
Fire Fighting Procedures:	Use water to cool fire-exposed containers.		
Specific Hazards Arising from the Chemical:	Decomposition may release oxides of carbon and butadiene.		
Precautions for Fire Fighters:	Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus.		
Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	HANDS	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Evacuate spill area and keep unprotected personnel away. Ventilate area. Wear appropriate protective clothing as described in Section 8. Avoid contact with skin, eyes or clothing.

Avoid breathing vapors.			
Environmental Precautions: Prevent entry into sewers and waterways. Report releases as required by local and national authorities.			
Methods and Materials for Containment and Clean-up: Promptly wipe up or scoop up spills and place in appropriate containers for disposal.			
Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	HANDS	RESPIRATORY	SKIN
			

7. HANDLING AND STORAGE

Precautions for Safe Handling: Avoid contact with the eyes, skin and clothing. Avoid breathing 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.

Conditions for Safe Storage: Store in a cool, dry, well-ventilated area away from incompatible materials. Keep container tightly closed.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:

Sodium Potassium Aluminosilicate	United States	None Established
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	Germany	None Established	
	United Kingdom	None Established	
	European Union	None Established	
1, 3 Butylene glycol	United States	None Established	
	Germany	None Established	
	United Kingdom	None Established	
	European Union	None Established	
Di(propylene) Glycol	United States	None Established	
	Germany	100 mg/m ³ (Inhalable, Sum of vapor and aerosol) TWA, 200 mg/m ³ STEL DFG MAK (Skin)	
	United Kingdom	None Established	
	European Union	None Established	
Biological Exposure Limits: None Established.			
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 to avoid contact. Specific Skin Protection: No special protection is required. 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
			
Environmental Exposure Controls: Do not allow spills to enter sewers or waterways.			
General Hygiene Considerations and Work Practices: Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling. Eye wash facilities should be available in the work area.			
Protective Measures During Repair and Maintenance of Contaminated Equipment: Wear appropriate protective clothing and equipment.			

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Paste in various colors	Explosive limits:	LEL: Not applicable UEL: Not applicable
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Odor:	Odorless	Vapor pressure (mmHg):	Not applicable
Odor threshold:	Not determined	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:	Insoluble in water (<0.1%)
Initial boiling point and range:	Not applicable	Partition coefficient: n-octanol/water:	Not available
Flash point:	Not applicable	Auto-ignition temperature:	Not applicable
Evaporation rate:	Not determined	Decomposition temperature:	Not determined
Flammability:	Not flammable	Viscosity:	Not determined
Explosive Properties:	Not explosive	Oxidizing Properties:	None
% Volatile by Volume:	Negligible		

10. STABILITY AND REACTIVITY

Reactivity: None known.

Chemical Stability: Stable. Does not degrade. Partially evaporates.

Possibility of Hazardous Reactions: None known.

Conditions to Avoid: None known.

Incompatible materials: Avoid strong oxidizing agents and reducing agents.

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

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:

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

<u>Chronic Health Effects:</u> None known.
<u>Carcinogenicity:</u> None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU Substances 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> Sodium Potassium Aluminosilicate: 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
<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

<u>Toxicity:</u> 1, 3 Butylene glycol: 48hr EC50 Daphnia magna - >1000 mg/L; 72hr ErC50 Algae - >1070 mg/L Di(propylene) Glycol: 48hr EC50 Daphnia magna - >109 mg/L
<u>Persistence and Degradability:</u> 1, 3 Butylene glycol: Readily biodegradable – 81% after 29 days.
<u>Bio-accumulative Potential:</u> No data available
<u>Mobility in Soil:</u> No data available
<u>Other Adverse Effects:</u> Possible hazardous long term degradation products may arise.
<u>Results of PBT/vPvB Assessment:</u> Not applicable.

13. DISPOSAL CONSIDERATIONS

<u>Regulations:</u> Dispose in accordance with all national and local regulations.
<u>Properties (Physical/Chemical) Affecting Disposal:</u> Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers.
<u>Waste Treatment Recommendations:</u> Dispose in accordance with national and local regulations.

14. TRANSPORT INFORMATION

UN Number:	ADR/RID: None	IMDG: None	IATA: None	DOT: None
UN proper shipping name:	ADR/RID: Not Regulated IMDG: Not Regulated IATA: Not Regulated DOT: Not Regulated			
Transport hazard class(es):	ADR/RID: None	IMDG: None	IATA: None	DOT: None
Packaging group:	ADR/RID: None	IMDG: None	IATA: None	DOT: None
Environmental hazards:	ADR/RID: No	IMDG Marine pollutant: No	IATA: No	DOT: No
Special precautions for user: Not applicable				

15. REGULATORY INFORMATION

U.S. Federal Regulations

US OSHA Hazard Classification: Not Hazardous

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): 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: 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 lists.

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.

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: 06 June 2013

Revision Summary: Updated SDS to current format.

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

DENTSPLY International

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010), US 29CFR1910.1200, Canada Hazardous Products Regulation

Date Issued: 15 November 2009

Document Number: 412

Date Revised: 19 April 2017

Revision Number: 2

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

1.1 Product Identifier:

Trade Name (as labeled):

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

Part/Item Number:

4300207, 4350301, 4350307-4350309, 4400301-4400346, 4400501-4400546, 4450301-4450346, 4450501-4450546, 4500301-4500313, 4550301-4550302, 4600301, 4600303, 4600314-4600326, 4600501, 4600514-4600516, 4600520-4600521, 4650315-4650316, 4650320, 4650515-4650516, 4650520, 4700301-4700316, 4720301-4720308, 4750300-4750301, 4750315-4750316, 4750326, 4740101-4740118, 4760301-4760304

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

Recommended Use:

Used in fabrication of dental crown, bridges, and laminated veneers.

Restrictions on Use:

For Professional Use Only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:

Dentsply Sirona Prosthetics

Manufacturer/Supplier Address:

570 West College Ave.

York, PA 17401

Manufacturer/Supplier Telephone Number:

717-845-7511 (Product Information)

Email address:

Prosthetics_MSDS@Dentsplysirona.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: Not classified as hazardous

2.2 Label Elements: Not 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 %
Sodium Potassium Aluminosilicate	Proprietary	Proprietary	Not Applicable	80-100
Tin Oxide	21651-19-4	244-499-5 /	Not Applicable	0-5

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 eyes with water, while holding the eyelids apart. Get medical attention if irritation persists.
Skin	Wash skin with soap and water. Remove and launder clothing before re-use.
Inhalation	Remove victim to fresh air. Get medical attention if irritation develops.
Ingestion	If small quantities are swallowed, rinse 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:

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

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

No immediate medical attention is required.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Use media appropriate for the surrounding fire.
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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.

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures/Precautions for Fire Fighters:	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. 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:

Evacuate spill area and keep unprotected personnel away. Eliminate all sources of ignition. 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.

6.2 Environmental Precautions:

Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

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 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. Minimize the generation and accumulation of dust. Keep dust away from open flames, hot surfaces and sources of ignition. 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: Store in a cool, dry, well-ventilated area away from heat, sources of ignition and 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:

Sodium Potassium Aluminosilicate	5 mg/m ³ (Respirable fraction), 15 mg/m ³ (Total dust)TWA OSHA PEL (as PNOC)
	4 mg/m ³ TWA DFG MAK (Inhalable) (As Dust, general threshold limit value)
	Belgium: 10 mg/m ³ TWA (as Dust, inhalable)
Tin Oxide	2 mg/m ³ TWA ACGIH TLV
Biological Exposure Limits: None Established	
8.2 Exposure Controls:	
<p>Appropriate Engineering Controls: Use with adequate general or local exhaust ventilation to minimize exposures levels. 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.</p>	
<p>Individual Protection Measures (PPE):</p> <p>Specific Eye/face Protection: Chemical safety glasses are recommended when handling, grinding, or polishing.</p> <p>Specific Skin Protection: Wear impervious gloves to protect hands when grinding or polishing.</p> <p>Specific Respiratory Protection: When grinding, polishing or where exposure levels are excessive, 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.</p> <p>Specific Thermal Hazards: None required.</p>	

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Powder in various colors	Explosive limits:	LEL: Not applicable UEL: Not applicable
Odor:	Odorless	Vapor pressure (mmHg):	Not applicable
Odor threshold:	Not determined	Vapor density:	Not applicable
pH:	Not applicable	Relative density:	2.4-3.1 mg/cc @ 20°C (68°F)
Melting/freezing point:	Not applicable	Solubility(ies):	Insoluble in water (<0.1%)
Initial boiling point and boiling range:	Not applicable	Partition coefficient: n-octanol/water:	Not applicable
Flash point:	Not applicable	Auto-ignition temperature:	Not applicable
Evaporation rate:	Not applicable	Decomposition temperature:	Not determined
Flammability (solid, gas):	Not Flammable	Viscosity:	Not applicable

Explosive Properties:	High concentrations of dust in the presence of an ignition source could result in a dust explosion.	Oxidizing Properties:	None
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9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.
10.2 Chemical Stability: Stable.
10.3 Possibility of Hazardous Reactions: No known dangerous reactions.
10.4 Conditions to Avoid: void heat, sparks, flames and all other sources of ignition. Avoid hygroscopic conditions and dust formation.
10.5 Incompatible materials: No known incompatible materials.
10.6 Hazardous Decomposition Products: No known decomposition products.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

<u>Potential Health Effects:</u> <u>Eyes:</u> Direct contact with powder may cause irritation with redness, burning and tearing. Dust from grinding or polishing may cause mechanical irritation. <u>Skin:</u> This product does not irritate skin. Non-sensitizing in Kligman Maximization Test. <u>Ingestion:</u> No adverse effects are expected from swallowing small amounts. This product was found to be non-toxic when tested with laboratory animals. This product was found to be non-irritating to mucous membranes in studies with laboratory animals. <u>Inhalation:</u> Not expected to cause respiratory tract irritation. Dust from grinding or polishing may cause sneezing, coughing, and other signs of mechanical irritation.
<u>Chronic Health Effects:</u> None known.
<u>Irritation:</u> No data available. This product is not expected to cause eye or skin irritation.
<u>Corrosivity:</u> This product is not corrosive.
<u>Sensitization:</u> None of the components have been shown to cause sensitization in animals or humans. Non-sensitizing in Kligman Maximization Test.
<u>Carcinogenicity:</u> None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP
<u>Mutagenicity:</u> No data is currently available.
<u>Aspiration Hazard:</u> Not an aspiration hazard.
<u>Acute Toxicity Data:</u> Sodium Potassium Aluminosilicate: No toxicity data available. Tin Oxide: No toxicity data available.

Reproductive Toxicity Data: No data available. This product is not expected to cause reproductive or developmental toxicity.

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

Specific Target Organ Toxicity Repeated Exposure (STOT-RE): No data available.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Sodium Potassium Aluminosilicate: No data is currently available

Tin oxide: No data is currently 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: None known

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Waste Treatment Recommendations: Treat 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 - product is transported only in packaged form.

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: Classified as per OSHA HazCom 2012 GHS in Section 2 of this SDS.

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: None known

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: 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 –1 Flammability – 0 Physical Hazard– 0

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

None

Supersedes: 12 March 2014

Date Updated: 19 April 2017

Revision Summary: 3 Year update. Changes to Sections 1, 8, & 11.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website, Country websites for occupational exposure limits.