

Safety Data Sheet

Safety Data Sheet conforms to Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 2020/878, US 29CFR1910.1200, Canada Hazardous Products Regulation Date Issued: 22 August 2016 Document Number: 001011 Date Revised: 13 December 2021 Revision Number: 4

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

1.1 Product Identifier:

Trade Name (as labeled): Dentsply Sirona Stain & Glaze Porcelain

Part/Item Number: Body Stain: 605520-605524; Incisal Stain: 605531-605532;

Universal Stain: 605500 – 605513;

Universal Overglaze: 605540; High-Flu: 605542

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

Recommended Use: Used in the fabrication of dental crowns and bridges.

Restrictions on Use: For Professional Use Only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: Dentsply Sirona
Manufacturer/Supplier Address: 1301 Smile Way

York, PA 17401

Manufacturer/Supplier Telephone Number: 717-845-7511 (Product Information)
Email address: Prosthetics-SDS@dentsplysirona.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number: 800-243-1942

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:

Not Required

Signal Word: None

Hazard Phrases	Precautionary Phrases
None Required	None Required

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS # / REACH Registration #	Classification	WT %
Crystalline Silica*	14808-60-7	238-878-4 /	STOT RE 1, H372 Carc. 1, H350	40-60
Di(propylene) Glycol	25265-71-8	246-770-3 /	Not applicable	10-25
Aluminum Oxide*	1344-28-1	215-691-6 /	Not applicable	1-10
Sodium Oxide*	1313-59-3	215-208-9 /	Skin Corr. 1B, H314	1-5
Boron Trioxide*	1303-86-2	215-125-8 /	Repro 1B, H360	0-10
Tin Oxide*	18282-10-5	242-159-0 /	Not applicable	0-10
Potassium Oxide*	12136-45-7	235-227-6 /	Eye Dam. 1, H318 Skin Corr. 1A, H314	1-5
Vanadium Zirconium Yellow Baddeleyite*	25265-71-8	246-770-3	Not applicable	1-5
Lithium Oxide*	12057-24-8	235-019-5 /	Eye Dam. 1, H318 Skin Corr. 1B, H314	<3
Barium Oxide*	1304-28-5	215-127-9 /	Oxid. Sol. 1, H271 <3 Acute Tox. 3, H301 LD50 100mg/kg Eye Dam. 1, H318 Skin Corr. 1B, H314	
Diterbium Trioxide*	12036-41-8	234-849-5 /	Eye Irt. 2, H319, <2 Skin Irt. 2, H315 STOT SE 3, H335	
Zircon praesodymium yellow*	68187-15-5	269-075-7	Not applicable	<2
Pigment Black 24*	68186-89-0	269-051-6	Skin Sens 1, H317 STOT RE 1, H372 Carc. 1A, H350	<2
Titanium Dioxide*	13463-67-7	236-675-5 /	Carc. 2, H351	<1

^{*}Note: These components in this product are inextricably bound together within a glass matrix. The dust produced during the handling of the porcelain powders 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	on of First Aid Measures:
Eye	Do not rub your eyes. Product powder may cause abrasive eye injury. Flush eyes thoroughly with water, holding open eyelids. Get medical attention if irritation persists.
Skin	Do not rub or scratch. Product powder may cause mechanical irritation. Wash exposed skin with soap and water. If skin irritation persists, get medical attention. Launder contaminated clothing before reuse.

Inhalation	If irritation develops, remove victim to fresh air.
Ingestion	No adverse effects expected.

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

This product is a non-hazardous, fine porcelain powder contained in an organic paste. Dust from the polishing or grinding of solid material may cause eye or respiratory tract irritation.

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

Immediate medical attention is not required.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Use media appropriate for surrounding fire.		
5.2 Special Hazards Arising from the Substance or Mixture:			
Organic component of paste n	Organic component of paste may burn under fire conditions. Burning may release oxides of carbon.		
5.3 Advice for Fire-Fighters:			
Fire Fighting Procedures/Precautions for Fire Fighters:	Use water to cool fire exposed containers and structures. Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus.		

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Wear appropriate protective clothing as described in Section 8 if exposed to spilled product as paste, or dust form if allowed to dry. Or dust from grinding or polishing solid product. Avoid contact with eyes. Avoid breathing dust or vapors.

6.2 Environmental Precautions:

Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

For paste spills: Scrape up product and transfer to a suitable container for disposal. Clean spill area.

For dust from the grinding or polishing of solid products: Contain spills, sweep or gather spilled material in a manner that minimizes the generation of airborne dusts, and transfer to a suitable container for disposal. Pick up solid product and transfer to a suitable container for disposal.

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:

Paste form: Avoid breathing vapors. Use with adequate ventilation.

Fired product: Avoid generating dust. Avoid breathing dust. Use adequate ventilation for polishing or grinding operations. Use good housekeeping to minimize accumulation of dust. Wash hands thoroughly after use.

Empty containers retain product residues. Follow all SDS precautions when handling empty containers.

7.2 Conditions for Safe Storage, Including Any Incompatibilities: Store in a tightly closed container in a cool, well-ventilated location away from incompatible materials. Store away from food or beverages.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:				
Occupational Exposure Limits:				
Crystalline Silica*	0.05 mg/m³ TWA OSHA PEL (respirable dust) 0.025 mg/m³ TWA ACGIH TLV (Respirable) 0.1 mg/m³ TWA UK WEL (as Silica, respirable crystalline) 0.1 mg/m³ TWA Belgium OEL			
Di(propylene) Glycol	100 mg/m³ TWA, 200 mg/m³ STEL DFG MAK			
Aluminum Oxide*	5 mg/m³ (respirable fraction), 15 mg/m³ (total dust) TWA OSHA PEL 1 mg/m³ TWA ACGIH TLV (Respirable) (as Aluminum, metal and insoluble compounds) 4 mg/m³ TWA DFG MAK (Inhalable) 1.5 mg/m³ TWA DFG MAK (Respirable) 10 mg/m³ (Inhalable) TWA UK WEL 4 mg/m³ (Respirable) TWA UK WEL			
Sodium Oxide*	None Established			
Boron Trioxide*	10 mg/m³ ACGIH TLV 15 mg/m³ OSHA PEL (total dust) 10 mg/m³ TWA, 20 mg/m³ STEL UK WEL 10 mg/m³ TWA Belgium OEL			
Tin Oxide (as Tin compounds)*	2 mg/m³ TWA ACGIH TLV (as Tin Oxides, as Sn) 2 mg/m³ TWA EU OEL (as Tin compounds, inorganic) 2 mg/m³ TWA, 4 mg/m³ STEL UK WEL (as Tin compounds, inorganic)			
Potassium oxide*	None established			
Vanadium Zirconium Yellow Baddeleyite (as Zirconium compounds)*	5 mg/m ³ TWA, 10 mg/m ³ STEL ACGIH TLV 5 mg/m ³ TWA OSHA PEL 1 mg/m ³ TWA, 1 mg/m ³ STEL DFG MAK (Inhalable) 5 mg/m ³ TWA, 10 mg/m ³ STEL UK WEL 5 mg/m ³ TWA, 10 mg/m ³ STEL Belgium OEL			
Lithium Oxide*	1 mg/m³ Ceiling AIHA WEEL 0.2 mg/m³ TWA, 0.2 mg/m³ STEL DFG MAK (Inhalable) (as lithium and compounds)			
Barium Oxide*	None Established			
Diterbium Trioxide*	None Established			
Zircon praesodymium yellow (as Zirconium compounds)*	5 mg/m ³ TWA, 10 mg/m ³ STEL ACGIH TLV 5 mg/m ³ TWA OSHA PEL 1 mg/m ³ TWA, 1 mg/m ³ STEL DFG MAK (Inhalable) 5 mg/m ³ TWA, 10 mg/m ³ STEL UK WEL 5 mg/m ³ TWA, 10 mg/m ³ STEL Belgium OEL			

Pigment Black 24*	None established	
Cobalt compounds – Pigment Black 24* (as Cobalt)	0.02 mg/m ³ TWA ACGIH TLV 0.1 mg/m ³ TWA OSHA PEL (for metal dust and fume) 0.1 mg/m ³ TWA UK WEL 0.02 mg/m ³ TWA Belgium OEL	
Nickel compounds - Pigment Black 24* (as Nickel)	0.2 mg/m³ TWA ACGIH TLV (Inhalable) 1 mg/m³ TWA OSHA PEL 0.03 mg/m³ TWA, 0.24 mg/m³ STEL DFG MAK (Inhalable) 0.5 mg/m³ TWA UK WEL 1 mg/m³ TWA Belgium OEL	
Manganese compounds - Pigment Black 24* (As Manganese)	0.02 mg/m³ TWA ACGIH TLV (Respirable) 0.1 mg/m³ STEL ACGIH TLV (Inhalable 5 mg/m³ Ceiling OSHA PEL 0.02 mg/m³ TWA, 0.16 mg/m³ STEL DFG MAK (Respirable) 2 mg/m³ TWA, 1.6 mg/m³ STEL DFG MAK (Inhalable) 10 mg/m³ TWA Belgium OEL 0.2 mg/m³ TWA (Inhalable), 0.05 mg/m³ TWA (Respirable) UK WEL 0.2 mg/m³ TWA (Inhalable), 0.05 mg/m³ TWA (Respirable) EU OEL	
Titanium Dioxide*	10 mg/m³ TWA ACGIH TLV 15 mg/m³ TWA (Total dust) OSHA PEL 0.3 mg/m³ TWA, 2.4 mg/m³ STEL DFG MAK (Respirable) 10 mg/m³ (Inhalable) TWA UK WEL 4 mg/m³ (Respirable) TWA UK WEL 10 mg/m³ TWA Belgium OEL	

^{*}Note: These components of this product are inextricably bound together within the glass matrix of this product and pose no risk of exposure during processing or handling.

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: Use ventilation that is adequate to keep employee exposure to airborne concentrations below exposure limits.

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: If needed, an approved respirator with high efficiency particulate filters may be used. For higher exposures, a supplied air respirator may be required. Respirator selection and use should be based on contaminant type, form and concentration. Follow 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:	White or colored paste	Explosive limits:	LEL: Not applicable UEL: Not applicable
Color:	White	Physical State:	Solid
Odor:	Odorless	Vapor pressure (mmHg):	Not available

Odor threshold:	Not applicable	Relative Vapor Pressure @20°C: (Air = 1)	Not applicable
рН:	Not applicable	Relative density:	Not available
Melting/freezing point:	Not available	Solubility(ies):	In water: Insoluble
Initial boiling point and boiling range:	Not applicable	Partition coefficient: n-octanol/water:	Not applicable
Flash point:	Not available	Auto-ignition temperature:	Not applicable
Evaporation rate: (n-BuAc = 1)	Not available	Decomposition temperature:	Not available
Flammability	Not flammable	Kinematic Viscosity:	Not available

9.2.1 Properties, Safety Characteristics and Test Results for Physical Hazards: None determined.

9.2.2 Other Safety Characteristics: None determined

10. STABILITY AND REACTIVITY

10.1 Reactivity: Non-reactive.

10.2 Chemical Stability: Stable under normal conditions.

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

10.4 Conditions to Avoid: None known.

10.5 Incompatible materials: Avoid oxidizing agents, strong acids, strong bases, ethylene oxide, halogenated hydrocarbon, and chlorine trifluoride.

10.6 Hazardous Decomposition Products: Irritating fumes and oxides may be released when product is heated.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Not classified as an eye irritant, but mechanical irritation may occur.

Skin: Not classified as a skin irritant, but mechanical irritation may occur.

Ingestion: May cause gastrointestinal effects.

Inhalation: No adverse effects expected. Vapors may cause mild respiratory irritation.

Chronic Health Effects: None expected.

Eye Irritation/ Damage: Based on available data, the classification criteria are not met.

Skin Irritation / Corrosivity: Based on available data, the classification criteria are not met.

Sensitization: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met. Crystalline silica quartz is listed as "Carcinogenic to Humans" (Group 1) by IARC; "Known to be a Human Carcinogen" by NTP; and an OSHA carcinogen. Nickel compounds are classified by IARC as known human carcinogens (Group 1) and by NTP as known human carcinogens. Metallic nickel is classified by IARC as possibly carcinogenic to humans (Group 2B) and by NTP as reasonably anticipated to be a carcinogen. Cobalt and cobalt compounds are classified by IARC as possibly carcinogenic to humans (Group 2B). Titanium dioxide is listed by IARC as a Group 2B carcinogen (Possibly carcinogenic to humans). Pigment Black 24 is classified as Carcinogen Category 1A in the EU. The components of this product are inextricably bound together during the glass melting/forming process during manufacturing. Therefore, there is no exposure to these materials 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: Based on available data, the classification criteria are not met.

Aspiration Hazard: Based on available data, the classification criteria are not met.

Acute Toxicity Data:

Crystalline Silica: Oral Rat LD50 - >22,500 mg/kg Di(propylene) Glycol: Oral rat LD50->5000 mg/kg

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

Sodium Oxide: No toxicity data available

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

Skin rabbit LD50->2000 mg/kg

Tin Oxide: Oral rat LD50 - >20,000 mg/kg, Inhalation rat LC50- >2.04 mg/L/4hr (no deaths)

Potassium Oxide: Not classified for acute toxicity.

Vanadium Zirconium Yellow Baddeleyite: Not classified for acute toxicity.

Lithium Oxide: Not classified for acute toxicity

Barium Oxide: Oral LD50- 100 mg/kg GHS Point Estimate Value,

Diterbium Trioxide: Not classified for acute toxicity

Zircon praesodymium yellow: Not classified for acute toxicity.

Pigment Black 24: Not classified for acute toxicity.

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

Reproductive Toxicity Data: Based on available data, the classification criteria are not met. Boron Oxide: In an 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 mating 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. Cobalt: In a 15 gestation study, rats were given 25, 50 and 100 mg/kg of cobalt powder. It was concluded that cobalt administered by gavage up to 100 mg/kg was not embryo toxic or teratogenic. Nickel: Metallic nickel may upset the hormonal balance of the mother and can impair the development of the preimplantation embryo. The metal can cross the feto-maternal barrier and enter the fetus. In addition to an increase in prenatal and neonatal mortality, nickel can produce different types of malformations in the surviving embryos and cause teratogenic effects.

The Boron oxide; and the Nickel and cobalt compounds within the Pigment Black 24 are bound in a glass matrix, exposure is unlikely.

Specific Target Organ Toxicity Single Exposure (STOT-SE):

Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity Repeated Exposure (STOT-RE):

Based on available data, the classification criteria are not met.

11.2 Information on Other Hazards

11.2.1 Endocrine Disrupting Properties: None known

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 is currently available

12.4 Mobility in Soil: No data is currently available

12.5 Results of PBT and vPvB Assessment: Not required

12.6 Endocrine disrupting Properties: None known.

12.7 Other Adverse Effects: None known

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Waste Treatment Recommendations: Dispose in accordance with all national and local regulations. Avoid generating airborne dust.

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 IMO Instruments: 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 has a Reportable Quantity (RQ) of 5,000 lbs. (based on the RQ for Nickel of 100 lbs. listed at <2%). Releases above the RQ must be reported to the National Response Center. 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): Antimony trioxide (as antimony compounds) is regulated under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories: See OSHA Hazard Classification in Section 2.

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Cobalt compounds at <2% Nickel compounds at <2%

State Regulations

California: This product contains chemicals including Titanium Dioxide, Crystalline Silica, Nickel and Cobalt, which are known to the State of California to cause cancer. However, these components in this product are bound within the glass matrix and no exposure can occur.

International Regulations

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

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.

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

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

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

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

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

Carc. 1 Carcinogen Category 1

Carc. 2 Carcinogen Category 2

Eye Dam. 1 Eye Damage Category 1

Eye Irt. 2 Eye Irritation Category 2

Oxid. Sol. 1 Oxidizing Solid Category 1

Repr. 1B Reproductive Toxicity Category 1B

Skin Corr. 1A Skin Corrosion Category 1A

Skin Corr. 1B Skin Corrosion Category 1B

Skin Sens. 1 Skin Sensitizer Category 1

STOT RE 1 Specific Target Organ Toxicity Repeated Exposure Category 1 STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3

H271 May cause fire or explosion; strong oxidizer

H372 Causes damage to organs through prolonged or repeated exposure.

H301 Toxic if swallowed.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction

H318 Causes serious eye damage.

H319 Causes serious eye irritation

H335 May cause respiratory irritation

H350 May cause cancer.

H351 Suspected of causing cancer.

H360 May damage fertility or the unborn child.

Supersedes: 17 September 2021 Date updated: 13 December 2021

Revision Summary: Composition revision. Changes to Sections 8, 11, 15, & 16.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website,

Country websites for occupational exposure limits.