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: 13 October 1997 Document Number: 125 Date Revised: 6 March 2015 Revision Number: 3

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

1.1 Product Identifier:

Trade Name (as labeled): Sonox[™] Ultrasonic Cleaner

Part/Item Number: 98941

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

Recommended Use: General Purpose Cleaner
Restrictions on Use: For Professional Use Only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:DENTSPLY ProstheticsManufacturer/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
Acute Toxicity Category 4 (H332)	Not Hazardous	Not Hazardous
Eye Damage Category 1 (H318)		
Skin Irritant Category 2 (H315)		
Specific Target Organ Toxicity –		
Repeated Exposure Category 2 (H373)		

EU Classification: Xi (Irritant), Xn (Harmful) R20/22, R41, R48/20/22

2.2 Label Elements:



Signal Word: Danger

Contains: Sodium Edetate, Surfactants

Hazard Phrases	Precautionary Phrases
H315 Causes skin irritation.	P260 Do not breathe dust, mists, or spray.
H318 Causes serious eye damage.	P264 Wash thoroughly after handling.
H332 Harmful if inhaled.	P270 Do not eat, drink or smoke when using this product.
H373 May cause damage to respiratory tract through	P271 Use only outdoors or in a well-ventilated area.
prolonged or repeated exposure by inhalation.	P280 Wear protective gloves and eye protection.
	P305 + P351+ P338 IF IN EYES: Rinse cautiously with
	water for several minutes. Remove contact lenses, if
	present and easy to do. Continue rinsing.
	P310 Immediately call a POISON CENTER or doctor.
	P302+P352 IF ON SKIN: Wash with plenty of soap and
	water.
	P332+P313 If skin irritation occurs: Get medical attention.
	P362 Take off contaminated clothing and wash before
	reuse.
	P304+P340 IF INHALED: Remove victim to fresh air and
	keep at rest in a position comfortable for breathing.
	P312 Call a POISON CENTER or doctor if you feel
	unwell.
	P314 Get medical attention if you feel unwell.
	P501 Dispose of contents and container in accordance with
	local and national regulations.

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Pentasodium Triphosphate	7758-29-4	231-838-7	Not Applicable	15-40
Sodium Edetate	64-02-8	200-573-9	Xi, Xn, R20/22, R41, R48/20/22 Acute Tox. 4, H302, H332 Eye Dam. 1, H318 STOT RE 2, H373	10-30
Sodium Carbonate	497-19-8	207-838-8	Xi R36 Eye Irrit. 2, H319	7-13
Surfactants	Proprietary	Proprietary	Xi R36/38 Skin Irrit. 2, H315 Eye Irrit. 2, H319	7-13
Sodium Lauryl Sulfate	151-21-3	205-788-1	Xn R22, R37/38, R41 Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT SE 3, H335	1-5

	Aq. Chronic 3, H412	

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 Descripti	on of First Aid Measures:
Eye	Immediately flush victim's eyes with large quantities of water for at least 20 minutes, while holding the eyelids apart. Get immediate medical attention.
Skin	Remove contaminated clothing. Wash skin with soap and water for several minutes. Get medical attention if irritation occurs. Launder clothing before re-use.
Inhalation	Remove to fresh air and keep at rest in a position comfortable for breathing. If breathing is difficult have qualified personnel administer oxygen. Get medical attention if you feel unwell.
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 large amounts are swallowed or if irritation or discomfort occurs, get medical attention.
4.2 Most Imp	portant Symptoms and Effects, Both Acute and Delayed:
	vere eye irritation and burns with possible eye damage. May cause moderate skin irritation. May cause act irritation. Harmful if inhaled. Prolonged inhalation to Sodium Edetate may damage respiratory tract.
4.3 Indicatio	n of Any Immediate Medical Attention and Special Treatment Needed:
Immediate m	edical attention is required for eye contact.
Note to Phys	icians (Treatment, Testing, and Monitoring): Treat symptomatically.

5. FIRE-FIGHTING MEASURES

This material is not combustib	5.2 Special Hazards Arising from the Substance or Mixture: This material is not combustible; however, contact with bare aluminum will generate flammable hydrogen gas. When heated to decomposition, carbon dioxide and carbon monoxide may form.				
5.3 Advice for Fire-Fighters		ie may form.			
Fire Fighting Procedures:	Cool fire exposed intact conta	Cool fire exposed intact containers and structures with water.			
Precautions for Fire Fighters:	Firefighters should wear full emergency equipment and an approved positive pressure self-contained breathing apparatus.				
	Recommended Protective E	Equipment for Fire Fighters:			
EYES/FACE	HANDS RESPIRATORY THERMAL				
Ey	Jan.		Th.		

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Prevent contact with eyes. Avoid contact with skin or clothing. Avoid breathing dust and mists. Always use with suitable protective clothing.

EYES/FACE	HANDS	RESPIRATORY	SKIN

6.2 Environmental Precautions:

Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Dust suppression methods should be used to clean up dust such as wet sweeping or vacuuming. Compressed air or dry sweeping methods should not be used. Place dry material into an appropriate container for disposal. Flush spill area with water to remove residue. For solutions: 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 Handing:

Prevent contact with eyes. Avoid prolonged contact with the eyes, skin and clothing. 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.

- **7.2 Conditions for Safe Storage, Including Any Incompatibilities:** Store in a tightly closed container in a well-ventilated location away from incompatible materials. Prevent contact with moisture. 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:

Pentasodium Triphosphate (as PNOC)	United States	5 mg/m ³ (respirable dust), 15 mg/m ³ (total dust) OSHA PEL
	Germany	4 mg/m ³ (Inhalable) DFG MAK
	United Kingdom	None established
	European Union	None established
Sodium Edetate	United States	5 mg/m³ (respirable dust), 15 mg/m³ (total dust) OSHA PEL
	Germany	4 mg/m ³ (Inhalable) DFG MAK
	United Kingdom	None established
	European Union	None established
Sodium Carbonate (as PNOC)	United States	5 mg/m³ (respirable dust), 15 mg/m³ (total dust) OSHA PEL
	Germany	4 mg/m³ (Inhalable) DFG MAK
	United Kingdom	None established
	European Union	None established
Surfactants(as PNOC)	United States	5 mg/m³ (respirable dust), 15 mg/m³ (total dust) OSHA PEL
	Germany	4 mg/m ³ (Inhalable) DFG MAK
	United Kingdom	None established
	European Union	None established
Sodium Lauryl Sulfate (as PNOC)	United States	5 mg/m³ (respirable dust), 15 mg/m³ (total dust) OSHA PEL
,	Germany	4 mg/m ³ (Inhalable) DFG MAK
	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 maintain exposures low or when dust might be generated.

Individual Protection Measures (PPE):

Specific Eye/face Protection: Chemical safety goggles are recommended for both powder and liquid form.

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

Specific Respiratory Protection: None should be needed for normal use. If the ventilation is inadequate, wear 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.

Specific Thermal Hazards: None required

	Recommended Perso	nal Protective Equipment	
EYES/FACE	HANDS	RESPIRATORY	SKIN

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	White powder. Clear, colorless liquid when in aqueous solution.	Explosive limits:	LEL: Not applicable UEL: Not applicable
Odor:	No odor	Vapor pressure (mmHg):	Not applicable
Odor threshold:	Not applicable	Vapor density:	Not applicable
pH:	9.5 @ 20°C (68°F)	Relative density:	Not available
Melting/freezing point:	101°C (214°F)	Solubility(ies):	>10% in water.
Initial boiling point and boiling range:	Not applicable	Partition coefficient: n-octanol/water:	Not applicable
Flash point:	Not applicable	Auto-ignition temperature:	Product is not self-igniting.
Evaporation rate:	Not applicable	Decomposition temperature:	Not available
Flammability (solid, gas):	Not flammable	Viscosity:	Not applicable
Explosive Properties:	Not explosive	Oxidizing Properties:	Not an oxidizer

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.

10.2 Chemical Stability: Stable under normal handling conditions.

10.3 Possibility of Hazardous Reactions: Sodium carbonate reacts violently with acid to form carbon dioxide.

10.4 Conditions to Avoid: Avoid heat.

10.5 Incompatible materials: Avoid oxidizing agents, acids, fluorine, phosphorous pentoxide, sulfuric acid, zinc, lithium, and bare aluminum.

10.6 Hazardous Decomposition Products: When heated to decomposition, carbon dioxide and carbon monoxide may form. Contact with aluminum generates flammable hydrogen gas.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: May cause severe irritation with redness, burning and tearing. Corneal damage is possible.

Skin: Contact may cause moderate skin irritation.

Ingestion: May be harmful if swallowed. May cause diarrhea, vomiting, and abdominal discomfort.

Inhalation: Harmful if inhaled. Inhalation of dust or mists may cause irritation of the nose, throat and upper respiratory tract.

<u>Chronic Health Effects:</u> Prolonged or repeated inhalation of sodium carbonate may cause nosebleeds, nasal congestion, erosion of the teeth, and perforation of the nasal septum, chest pain and bronchitis.

<u>Irritation:</u> Sodium Edetate: Found to be irritating and corrosive to rabbit eyes and not irritating to rabbit skin. Sodium Carbonate: Not irritating to rabbit skin and irritating to rabbit eyes. Sodium Lauryl Sulfate: Irritating to rabbit skin and rabbit eyes.

<u>Corrosivity:</u> Sodium Edetate: Found to be corrosive to rabbit eyes. Sodium Lauryl Sulfate: Is classified as corrosive to rabbit eyes.

Sensitization: No data available. The components of this product are not skin sensitizers.

<u>Carcinogenicity:</u> None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

Mutagenicity: No data available.

Medical Conditions Aggravated by Exposure:

Individuals with pre-existing eye and respiratory disorders may be at increased risk from exposure.

Acute Toxicity Data:

Pentasodium Triphosphate: Oral rat LD50: 3900 mg/kg, Inhalation rat LC50: >0.39 mg/L/4hr (no deaths), Dermal rabbit

LD50: >4640 mg/kg

Sodium Edetate: Oral rat LD50: 1780 mg/kg

Sodium Carbonate: Oral rat LD50: 2800 mg/kg; Inhalation rat LC50: 2300 mg/m3/2 hrs; Dermal rabbit LD50: >2000 mg/kg

Surfactants: No toxicity data available

Sodium Lauryl Sulfate: Oral rat LD50: 977 mg/kg, Skin rat LD50: >2000 mg/kg

Product Oral ATE: 3757 mg/kg

Product Inhalation ATE: 5 mg/L (as dust)

Reproductive Toxicity Data: No data available

Specific Target Organ Toxicity (STOT):

Single Exposure: No data available.

Repeated Exposure: Sodium Edetate: Inhalation exposure to 1000 mg/m³ disodium EDTA for 6 hours caused lethality in 6 out of 20 male rats. Histological examination of the lung of the dead rats revealed congestion, edema, multifocal hemorrhages and inflammatory cell infiltrates. Inhalation exposure of rats to disodium EDTA for 6 hours per day, 5 consecutive days cause concentration dependent lesions in the larynx and lungs that were fully reversible within 14 days. Due to histopathological changes in the low dose group a no observed effect level could not be determined.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Sodium Carbonate: Bluegill Sunfish 96hr LC50: 320 mg/L; Daphnia magna 48hr EC50: 227 mg/L

Sodium Edetate: Lepomis macrochirus 96hr LC50: 792 mg/L

This product is not expected to harm the environment.

12.2 Persistence and Degradability: No data is currently available

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 Other Adverse Effects: None known

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with all national and local regulations.

Properties (Physical/Chemical) Affecting Disposal: Follow all SDS precautions when handling empty containers.

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	None
ADR/RID	None	Not Regulated	None	None	None
IMDG	None	Not Regulated	None	None	None
IATA/ICAO	None	Not Regulated	None	None	None

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 has an RQ of 12,500 lbs (based on the RQ of 5000 lbs for Pentasodium Triphosphate present 15-40%). Report spills required under federal, state and local regulations.

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

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:	Yes	Pressure Hazard:	No

Delayed Hazard:	Yes	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): Class D Division 2B (A toxic material causing other effects).

Canadian Environmental Protection Act: All of the components of this product are listed on the 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 of this product are listed on EINECS.

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

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

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

Korean Existing Chemicals List: All of the components of this product are listed on KECL

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 3 Flammability – 0 Physical Hazard– 0

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

Xi Irritant

Xn Harmful

R20/22 Harmful by inhalation and if swallowed.

R21/22 Harmful in contact with skin and if swallowed.

R22 Harmful if swallowed.

R36 Irritating to the eyes.

R41 Risk of serious damage to eyes.

R48/20/22 Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed.

Acute Tox. 4 Acute Toxicity Category 4 Eye Dam. 1 Eye Damage Category 1

Eye Irrit. 2 Eye Irritant Category 2

STOT RE 2 Specific Target Organ Toxicity Repeated Exposure Category 2

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

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

Supersedes: 14 September 2007

Revised: 6 March 2015

Revision Summary: Updated composition and all sections.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau,

ESIS, Country websites for occupational exposure limits.