DentsplySirona Safety Data Sheet

1. Identification

Product Name	SDS Code Number
Calm-It [™]	51A898
Trade Name & Synonyms	Date of Last Revision
Calm-It Dentin Desensitizer Solution	11/18/19
Manufacturer:	Address
DENTSPLY Milford	38 West Clarke Avenue
	Milford DE 19963-1805
	http://www.dentsplysirona.com
Grades or Minor Variant Identities	Company Telephone Number (Product Inquiries) (302) 422-4511
Not Applicable	(8:00 AM – 4:30 PM Eastern Time)
Product Use (for Canada)	Emergency Telephone Number
Not Applicable	CHEMTREC: 1-800-424-9300 (24 hours)
	(Outside U.S. +1-703-527-3887) CCN6510

2. Hazard(s) Identification



WARNING CAUSES SKIN IRRITATION

Wash hands thoroughly after handling.

Wear protective gloves

IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get Medical Advice/attention. Take off contaminated clothing and wash before reuse.

3. Composition/Information on Ingredients

Hazardous Components	C.A.S. Number	Exposure Limits	%
2-Hydroxyethyl methacrylate	868-77-9	N.E.	< than 45
Glutaraldehyde	111-30-8	0.05 ppm	< than 10

4. First Aid Measures

Routes of Exposure	First Aid Instructions	Immediate Medical Attention	Delayed Effects	
Eye	Rinse opened eye for several minutes under running water. If symptoms persist	Not Applicable	Not Applicable	
-	consult physician			
Skin	Immediately wash with soap and water and rinse thoroughly	Not Applicable	Not Applicable	
Inhalation	Supply fresh air, consult physician if symptoms persist	Not Applicable	Not Applicable	
Ingestion	Consult physician immediately	Not Applicable	Not Applicable	
Other	Not Applicable Not Applicable Not Applicable			
Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically.				

5. Fire Fighting Measures

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Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air	Autoignition Temperature: Not Applicable.	Other: Not Applicable
	LEL: Not Applicable UEL: Not Applicable	Product will not autoignite.	
Flame Propagation or Burning Rate	Properties Contributing to Fire Intensity: Not	Flammability Classification: Not Applicable	
(for Solids): Not Applicable	Applicable		
Extinguishing Media: CO ₂ , extinguishi	ng powder, foam carbon dioxide or water spray.	Extinguishing Media to Avoid: Water with full jet.	
Fight larger fires with water spray or alcohol resistant foam.			
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.			
Unusual Fire and Explosion Hazards: Formation of toxic, irritating gases is possible from the decomposition of the dimethacrylate resins.			
Product does not present an explosion hazard.			

6. Accidental Release Measures

	Containment Techniques: Absorb with liquid –binding material, (sand, diatomaceous earth, universal binders, sawdust).				
	Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container.				
Avoid gross skin contact to minimize the possibility of contact dermatitis to susceptible persons. Ensure adequate ventilation.					
ſ	Evacuation Procedures: Not Applicable Special Instructions: Not Applicable Reporting Requirements: Not Applicable				

7. Handling and Storage

Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals.

Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Protect from exposure to direct light. Store away from food and beverages.

8. Exposure Control / Personal Protection









Ventilation: None required during normal intended use of this product				
Other Engineering Cont	rols: Local ventilation if large amounts are used.			
Individual Protection	Personal Protective Equipment for Normal Use	Personal Protective		
Measures		Equipment for Emergencies		
Eye/Face	Safety Glasses	Not Applicable		
Skin	The glove material has to be impermeable and resistant to the product.	Not Applicable		
Inhalation	Not Required	Not Applicable		
Body Protection	Protective work clothing	Not Applicable		
General Hygiene Considerations and Work Practices: Keep away from foodstuffs, beverages and feed. Immediately remove all				
soiled and contaminated clothing. Wash hands before breaks and at end of work. Avoid contact with the eyes and skin.				
Protective Measures During Repair and Maintenance of Contaminated Equipment: Not Applicable				
Other Protective Measures and Equipment: Not Applicable				
ACGIH TLV: Glutaraldehyde (CAS 111-30-8), STEL = 0.05 ppm				

9. Physical and Chemical Characteristics

Appearance: Colorless liquid		Odor: Slight fruity odor
Normal Physical State: Liquid		Melting Point: Not Applicable
Specific Gravity: 1.04 g/cm ³	Solubility in Water: miscible with water	pH: 3.8 at 22°C
Vapor Pressure (mm Hg): Not Applicable	Vapor Density (AIR=1): Not Applicable	Evaporation Rate (Butyl Acetate =1):
		Not Applicable
Other: Not Applicable		

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong oxidizing agents, strong bases			
Hazardous Products Produced During Decomposition: No dangerous decomposition products known if used according to Directions for Use.			
Hazardous Polymerization: May Occur May Not Occur Conditions to Avoid: Extreme prolonged heat			
Stability? Stable □Unstable Conditions to Avoid: Extreme prolonged heat			

11. Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data:
Product is an irritant to the skin and mucous membranes. On the eye the product has an irritating effect. Sensitization: Repeated or prolonged skin contact or inhalation may cause sensitization for persons allergic to methacrylates and aldehydes. This product shows the following dangers according to internally approved calculation methods for composite materials: Irritant.

Emergency Overview: Material is irritating to eyes, respiratory system and skin.

Routes of		Single, Repeated, or	Severity (Mild,	Acute and Chronic Health Effect(s)	Target Organ(s)
Exposure	Signs and Symptoms	Lifetime Exposure	Moderate, Severe)		
Eye	Material can cause irritation.	Single	Moderate	Irritation and possible corneal damage	Not Applicable
Skin	Material may cause sensitization	Single & Repeated	Moderate	Irritation or possible allergic response. Severe allergic response may result in breathing difficulties.	Not Applicable
Inhalation	Material maybe harmful if inhaled	Single & Repeated	Mild	May cause chemical burns to the respiratory tract	Not Applicable
Ingestion	Material harmful if swallowed	Single & Repeated	Moderate	Potential gastrointestinal tract burns	Not Applicable
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable

Medical Conditions Aggravated by Exposure Open sores and wounds of the skin.

Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No. All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.

Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.

NFPA Hazard Classification Ratings (Scale 0-4) Health = 1, Fire = 1, Reactivity= 0 Specific Hazard = None

12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system

13.Disposal Considerations

Regulations: Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations Properties (Physical/Chemical) Affecting Disposal: Dispose of material in a closed container.

14.Transport Information

Regulated for Shipping: No	Proper Shipping Name: Not Regulated		Packing Group: Not Applicable
Do Changes in Quantities, packaging, or shipment		Hazard Class: Not Applicable	UN Identification Number: Not Applicable
method change product classification? No			

15.Regulatory Information

This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations.

U.S. Federal Regulations: CERCLA 103 Reportable Quantity: 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

Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements

Under SARA Title III, Section 313 (40 CFR 372): None

Section 302 Extremely Hazardous Substances (TPO): None

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

U.S. State Regulations California Proposition 65: This product does not contain any chemicals, which are on the California Proposition 65 list.

International Regulations: Canadian Environmental Protection Act:

This product is a medical device and not subject to chemical notification requirements.

European Community Labeling: Not a dangerous preparation.

European Inventory of New and Existing Chemicals Substances (EINECS):

This product is a medical device and not subject to chemical notification requirements.

Other: Not Applicable

16.Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex. All components are synthetically produced; none are derived from animal products.

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.