Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 22 June 2009
Document Number: 0070050MS
Date Revised: 21 May 2014
Revision Number: 5

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

1.1 Product Identifier:

Trade Name (as labeled):	**SensiTemp® NEZO Temporary Cement**
Part/Item Number:	70050, 70055

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

Recommended Use:	Temporary cement for restorations
Restrictions on Use:	For professional use only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:	Sultan Healthcare
Manufacturer/Supplier Address:	1301 Smile Way York, PA, USA
Manufacturer/Supplier Telephone Number:	1-201-871-1232 or 800-637-8582 (Product Information)-
Email address:	customer.service@sultanhc.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number:	800-535-5053 (INFOTRAC) 1-352-323-3500 (Outside the United States – Call Collect)

2. HAZARD(s) IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:

Health	Environmental	Physical
Skin Corrosive Category 1 (H314) Eye Damage Category 1 (H318)	Aquatic Acute Category 1 (H400) Aquatic Chronic Category 1 (H410)	Not hazardous

EU Classification (1999/45/EC as amended): Corrosive (C), Dangerous for the Environment (N)
EU Risk (R) Phrases: R34, R50/53
Refer to Section 16 for the full text of the EU Classifications and R Phrases.

Labeling Elements: Contains Nonanoic acid

Signal Word: Danger

Hazard Statements	Precautionary Statements
H314 Causes severe skin burns and eye damage. H410 Very toxic to aquatic life with long lasting effects.	P260 Do not breathe dust or mists. P264 Wash thoroughly after handling. P273 Avoid release to the environment. P280 Wear protective gloves, protective clothing, eye protection and face protection. P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with soap and water. P310 Immediately call a POISON CENTER or doctor P363 Wash contaminated clothing before reuse. P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P310 Immediately call a POISON CENTER or doctor. 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 P391 Collect spillage. P405 Store locked up. P501 Dispose of contents and container in accordance with local and national regulations.

2.3 Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.2 Mixture

Hazardous Components	C.A.S. # EC#	IUPAC Name	CLP/GHS / EU Classification (1272/2008) (1999/45/EC)	WT %
Base				

Zinc Oxide	1314-13-2 / 215-222-5	oxozinc	Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) N R50/53	60-80
Zinc Stearate	557-05-1 / 209-151-9	zinc octadecanoate	Aquatic Acute 1 (H400) Not dangerous	1-2
Potassium Nitrate	7757-79-1 / 231-818-8	potassium nitrate	O, R8	1-5

Catalyst				
Nonanoic acid	112-05-0 / 203-931-2	nonanoic acid	Skin Corr 1B (H314) Eye Dam 1 (H318) C, R34	40-50
Crystalline Silica, Quartz	14808-60-7 /	dioxosilane	Carc.1 (H350) * Not dangerous	1-10

*Crystalline silica, quartz is classified as a carcinogen in the United States. Since the crystalline silica is bound in the polymer matrix and no exposure is expected, the classification of the substance is not considered in the mixture classification.

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

4.1 Description of First Aid Measures:

Routes of Exposure	First Aid Instructions
Eye	For contact with catalyst, immediately flush eyes with large quantities of water for at least 30 minutes, holding the eyelids apart. Get immediate medical attention. For contact with base or reacted product, rinse eyes thoroughly with water, holding the eyelids apart. Get medical attention if irritation persists.
Skin	For contact with catalyst, immediately flush skin with water for 15 minutes while removing contaminated clothing. Wash skin thoroughly with soap and water. Get immediate medical attention. For contact with base or reacted product, Wash skin with soap and water. Get medical attention if irritation persists.
Inhalation	None needed under normal use conditions. If symptoms develop, immediately remove to fresh air. If breathing is difficult have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration. Get immediate medical attention for breathing difficulties**.**
Ingestion	If base or catalyst is swallowed, immediately call a poison control center. Only induce vomiting if directed by medical personnel. Never give anything by mouth to an unconscious person.

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

Catalyst - Causes burns to the eyes and skin. Inhalation of vapors may cause respiratory tract irritation or burns. Ingestion may cause burns to the mouth, throat and stomach with possible perforation of the digestive tract. Contains crystalline silica. Inhalation of respirable crystalline silica may cause lung disease and cancer. The crystalline silica in this product is encapsulated in a rosin and no exposure is expected to occur.

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

If eye or skin contact occurs, get immediate medical attention. If swallowed, get immediate medical attention.
Note to Physicians (Treatment, Testing, and Monitoring): Treatment of overexposure should be directed at the control of symptoms and clinical conditions.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media	
Use water spray, carbon dioxide, alcohol foam or dry chemical.	
5.2 Special Hazards Arising from the Substance or Mixture:	
None known.	
5.3 Advice for Fire-Fighters:	
Fire Fighting Procedures:	Cool fire exposed containers and structures with water.
Precautions for Fire Fighters:	Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

Recommended Protective Equipment for Fire Fighters:

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:			
Wear appropriate protective clothing, gloves and eye protection.			
Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	**SKIN**	**RESPIRATORY**	**THERMAL**
			

6.2 Environmental Precautions:

Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Collect using an inert non-combustible absorbent material and place in appropriate containers 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 Handing:

This is a two part product. Prevent contact with the eyes, skin and clothing with catalyst. Avoid breathing vapors, or mists. Wear appropriate protective clothing and equipment. Use only with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.

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 accordance with package instructions.

7**.3 Specific End Use (s):** For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Zinc Oxide	United States	5 mg/m3 TWA OSHA PEL (respirable) 2 mg/m2 TWA ACGIH TLV (respirable), 10 mg/m3 STEL (respirable)
	Germany	0.1 mg/m3 TWA DFG MAK (respirable) 2 mg/m3 TWA (inhalable)
	United Kingdom	None Established
	France	5 mg/m3 TWA INRS VME
	Spain	10 mg/m3 TWA VLA-ED (dust)
	Italy	None Established
	European Union	None Established
Zinc Stearate	United States	5 mg/m3 TWA OSHA PEL (respirable) 10 mg/m2 TWA ACGIH TLV
	Germany	0.1 mg/m3 TWA DFG MAK (respirable) 2 mg/m3 TWA (inhalable)
	United Kingdom	4 mg/m3 TWA UK OEL (respirable), 10 mg/m3 TWA (inhalable)
	France	10 mg/m3 TWA INRS VME
	Spain	None Established
	Italy	None Established
	European Union	None Established

Potassium Nitrate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Nonanoic acid	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Crystalline Silica, Quartz	United States	.025 TWA ACGIH TLV (respirable) 10 mg/m3 TWA US OSHA PEL (respirable dust) % SiO_2 +2
	Germany	None Established
	United Kingdom	0.1 mg/m3 TWA UK OEL
	France	0.1 mg/m3 TWA INRS VME
	Spain	0.1 mg/m3 TWA VLA-ED(respirable fraction)
	Italy	None Established
	European Union	None Established
Biological Exposure Limits: None Established		

8.2 Exposure Controls:

Appropriate Engineering Controls: No special controls required.

Individual Protection Measures (PPE)

Specific Eye/face Protection: Chemical safety goggles recommended for handling unreacted product. **Specific Skin Protection:** Wear impervious gloves to prevent skin contact with unreacted product. Recommended glove: Nitrile. Consult glove supplier for thickness and breakthrough times.
Specific Respiratory Protection: None required under normal use conditions.
Specific Thermal Hazards: Not applicable

Recommended Personal Protective Equipment:

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Off White paste	**Explosive limits:**	Not applicable
Odor:	Odorless	**Vapor pressure:**	Not available
Odor threshold:	Not available	**Vapor density:**	Not available
pH:	Not available	**Relative density:**	>1.0
Melting/freezing point:	Not available	**Solubility:**	Insoluble
Initial boiling point and range:	Not available	**Partition coefficient: n-octanol/water:**	Not available
Flash point:	Not flammable	**Auto-ignition temperature:**	Not available
Evaporation rate:	Not available	**Decomposition temperature:**	Not available
Flammability:	Not flammable	**Viscosity:**	Not available
Explosive Properties:	LEL: 1.2% (nonanoic acid)	**Oxidizing Properties:**	None

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: No unusual reactivity.

10.2 Chemical Stability: Stable.

10.3 Possibility of Hazardous Reactions: Hazardous reactions are unlikely.

10.4 Conditions to Avoid: Avoid excessive heat.

10.5 Incompatible materials: Avoid oxidizing agent.

10.6 Hazardous Decomposition Products: Thermal decomposition may produce carbon, nitrogen and zinc oxides

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Catalyst: Corrosive. Causes severe irritation or burns with redness, pain and tearing. Permanent damage may occur. Base and reacted product: May cause eye irritation.

Skin: Catalyst: Cause severe irritation or burns. Base and reacted product: May cause irritation.

Ingestion: Catalyst: Swallowing may cause burns to the mouth, throat and stomach with possible perforation of the digestive tract. Base and reacted product: May cause gastrointestinal upset.

Inhalation: Catalyst: None expected from normal use. Inhalation of vapors may cause irritation of mucous membranes and upper respiratory tract with coughing and sore throat. Severe exposure may cause pulmonary edema. Base and reacted product: No adverse effects are expected.

Chronic Health Effects: Repeated inhalation of crystalline silica may cause lung damage, silicosis and lung cancer. The crystalline silica in this product is encapsulated in a rosin so exposure is not expected.

Carcinogenicity: Crystalline silica is classified as a Group 1 carcinogen by IARC, and "known to be a human carcinogen" by NTP. None of the other components are listed as carcinogens by OSHA, IARC, ACGIH, NTP or EU Substances Directive.

Mutagenicity: Nonanoic acid was negative in the AMES test. Potassium nitrate was negative in the AMES test, Bacillus subtilis recombination assay and in mammalian cell gene mutation assay in Chinese hamsters and human lung cells.

Medical Conditions Aggravated by Exposure: Employees with pre-existing skin disorders may be at increased risk from exposure.

Acute Toxicity Data:

Zinc Oxide: Oral rat LD50 >5 g/kg

Zinc Stearate: No toxicity data available

Potassium Nitrate: Oral rat LD50 3,015 mg/kg

Nonanoic acid: Oral mouse LD50 15,000 m/kg, Skin rabbit >5,000 mg/kg.
Crystalline Silica: Oral rat LD50: >10,000 mg/kg; Inhalation rat LC50: >0.139 mg/l/4h; Skin rabbit LD50: >5,000 mg/kg

Reproductive Toxicity Data: Nonanoic acid: In a reproductive study, rats were administered during day 6-15 of gestation. No effects were seen on mortality, clinical signs, body weight changes, food consumption and gross pathology. The NOAEL for maternal and developmental toxicity was 1,500 mg/kg/day. Potassium nitrate was orally administered to mice at 0.4-400.mg/kg for 10 days. No significant differences were noted between the treated and control groups. NOAEL for maternal and teratogenic is 400 mg/kg.

Specific Target Organ Toxicity (STOT):

Single Exposure: Nonanoic acid is classified in EU CLP Annex VI as corrosive. In an irritation study using method OECD 404 it was shown to be irritating to skin. Nonanoic acid severely irritating to rabbit eyes. Various concentrations of nonanoic acid in 1-propanol were applied to 116 volunteers in a patch test study. A dose of 20% produced skin irritation, erythema at 48 hours and pigmentation at 96 hr. Zinc oxide is irritating to rabbit eyes and rabbit skin. Zinc Stearate is not irritating to rabbit eyes and rabbit skin.

Repeated Exposure: In an oral study, rats were given 5.0 mg/kg of zinc oxide for 6 months. Histology examination showed mild damage to the kidneys and moderate effects to the spleen. The LOAEL was determined to be 5.0 mg/kg.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Zinc Oxide: 96 hr LC50 Oncorhynchus mykiss (Rainbow trout) 1.1 ppm

Zinc Stearate: No data available

Potassium Nitrate: 48 hr LC50 daphnia magna 490 mg/L, 96 hr LC50 gambusia affinis (western mosquitofish) 22,500 ug/L

Nonanoic acid: 96 he LC50 Pimephales promelas (fathead minnow) 104 mg/L; 48 hr EC50 daphnia magna 96,000 ug/L

12.2 Persistence and Degradability: Nonanoic acid is readily biodegradable (99% in 5 days).

12.3 Bio-accumulative Potential: Nonanoic acid is not expected to bioaccumulate in aquatic organisms.

12.4 Mobility in Soil: Nonanoic acid is expected to have a low mobility in soil.

12.5 Other Adverse Effects: Zinc oxide is classified as very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

12.6 Results of PBT/vPvB Assessment: Not required.

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

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

Properties (Physical/Chemical) Affecting Disposal: None known.

Waste Treatment Recommendations: None needed for normal anticipated use.

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	UN3265	Corrosive solid, acidic, organic, n.o.s. (Nonanoic acid)	8	PG III	No
ADR/RID	UN3261, UN3077	Corrosive solid, acidic, organic, n.o.s. (Nonanoic acid), Environmentally Hazardous Substance, solid n.o.s. (zinc oxide)	8, 9	PG III, PG III	Yes
IMDG	UN3261, UN3077	Corrosive solid, acidic, organic, n.o.s. (Nonanoic acid), Environmentally Hazardous Substance, solid n.o.s. (zinc oxide)	8, 9	PG III, PG III	Yes, Marine Pollutant
IATA/ICAO	UN3261, UN3077	Corrosive solid, acidic, organic, n.o.s. (Nonanoic acid), Environmentally Hazardous Substance, solid	8, 9	PG III, PG III	Yes

		n.o.s. (zinc oxide)			

14.6 Special precautions for user: Corrosive solid
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

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): This product is a drug and not subject to chemical notification requirements.

Clean Water Act (CWA): Not Listed

Clean Air Act (CAA): Not Listed

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:	**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 %
Zinc Oxide (Zinc Compounds)	1314-13-2	60-80
Zinc Stearate (Zinc Compounds)	557-05-1	1-2

State Regulations

California: This product contains the following chemicals(s) known to the State of California to cause cancer, birth defects or reproductive harm:

Components	C.A.S. #	WT %
See Note below		

Note: The crystalline silica quartz in this product is bound in a polymer matrix and no exposure is expected. No warning under California Proposition is required.

International Regulations

EU REACH: The substances in this product comply with the EU REACH regulation as applicable.

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3:
C Corrosive
N Dangerous for the Environment
R34 Causes burns.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Skin Corr 1B Skin Corrosion Category 1
Eye Dam 1 Eye Damage Category 1
Carc.1 Carcinogen Category 1
Aquatic Acute 1 Aquatic Acute Category 1
Aquatic Chronic 1 Aquatic Chronic Category 1
H314 Causes severe skin burns and eye damage.
H318 Causes serious eye damage
H350 May cause cancer.
H400 Very toxic to aquatic life. H410
H410 Very toxic to aquatic life with long lasting effects.

Supersedes: : 21 May 2012
Revision Summary: Comprehensive review, new format

Date of SDS Preparation/Revision: 21 May 2014

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