

SAFETY DATA SHEET

Section 1 –Identification

Product Name: Simpurity Silver Calcium Alginate Dressings
Product Size: rope, 2" x 2", 4" x 5", 8" x 8"
Product Numbers: 51712, 51702, 51720, 51764
Manufacturer: Safe n Simple
Address: 5827 Terex
City: Clarkston
State: MI
ZIP: 48346
Country: US
Phone Number: Toll Free: 844-767-6334
Date Revised: 30th Nov, 2014

Section 2: Composition/Information on the Components

Component Name	CAS#/Codes	Concentration	Classification
Calcium Alginate/Silver	n/a	> 99%	None
Polysorbate 20	9005-64-5	< 1%	n/a

Section 3: Hazard Identification

Main hazards: Not classified as hazardous.
Carcinogenic Status: Not considered carcinogenic by NTP, IARC & OSHA.
Health Effects—Eyes: No adverse effects expected.
Health Effects—Skin: No adverse effects expected.
Health Effects—Ingestion: A large dose may cause diarrhea.
Health Effects—Inhalation: Exposure to dust at high concentrations may cause obstruction & difficulty in breathing.

Section 4: First Aid Measures

Eyes: Flush eyes with plenty of water, holding the eye open. Seek medical attention if symptoms persist.
Skin: This product is intended to be in contact with skin when used as directed. If irritation develops, seek medical attention.

Ingestion: No adverse effects expected. Drink 1-3 glasses of water to dilute stomach contents. Never administer anything by mouth if person is losing consciousness, is unconscious or convulsing—seek medical attention immediately.

Inhalation: Move patient to fresh air. If there is difficulty in breathing, give oxygen. Seek medical attention if symptoms persist.

Health Effects — Inhalation: Exposure to dust at high concentrations may cause obstruction & difficulty in breathing.

Physician Advice: Treat symptomatically. Some individuals, e.g. with asthma, may be intolerant to high concentrations of fiber in the air.

Section 5: Fire-fighting

General information: Will not support flaming combustion in normal circumstances. Sustained application of heat or flame to the dressing may cause a self-sustaining glow which can be extinguished using water.

Extinguishing Media: Water spray, carbon dioxide, dry chemical powder or foam

Hazardous combustion products: The product decomposes on application of heat. The fumes should not be inhaled. Combustion products are similar to those of cellulosic fibers, i.e. mainly carbon monoxide, carbon dioxide & water.

Unusual Fire or Explosion Hazards: Avoid the formation of dust clouds.

Protective Equipment for Fire-Fighting: Wear full protective clothing & self-contained breathing apparatus.

Section 6: Accidental Release Measures

Sweep into suitable containers for disposal. No specific measures necessary.

Section 7: Handling & Storage

Store in a cool, dry, well-ventilated location (<77° F/25° C)

Section 8: Exposure Control/Personal Protection

Occupational Exposure Standards: An exposure limit to calcium alginate dust is the same as other particulates — total of 10 mg/m³

Section 9: Physical & Chemical Properties

Physical State: Solid Fibers Color: white/off-white/grey

Odor: none pH: neutral

Boiling Point: n/a Melting Point: n/a

Flash Point: n/a Auto-flammability: above 200

Explosion Limits: n/a Vapor Pressure: n/a
Solubility in Water: not soluble Density: 1.75 g/cm³

Section 10: Stability & Reactivity

Stability: stable Materials to Avoid: none known
Conditions to avoid: Stable under normal conditions. Note that the fiber will gel or dissolve in aqueous solutions containing sodium or certain other ions. Avoid storage at high temperatures.

Section 11: Toxicological Information

The results of hemolysis, cytotoxicity, acute systemic toxicity and skin irritation studies as listed below, carried out on sterilized product, do not provide any evidence that the product is toxic. Likewise, the product does not cause contact sensitization on repeated application.

Hemolysis US National Formulary XIV

Cytotoxicity ISO 10993—Part 5

Acute Systemic toxicity ISO 10993—Part 11

Skin irritation ISO 10993—Part 10

Contact sensitization ISO 10993—Part 10

Calcium alginate is approved by the FDA as a food additive (21.CFR.184.1187).

Chronic toxicity/Carcinogenicity: Product not expected to cause long term adverse health effects.

Genotoxicity: Product not expected to cause any mutagenic effects.

Reproductive/Developmental Toxicity: Product not expected to cause any reproductive or developmental health effects.

Section 12: Ecological Information

Mobility: No relevant studies identified.

Persistence/Degradability: The product is readily biodegradable.

Bio-accumulation: No relevant studies identified.

Ecotoxicity: No relevant studies identified. Based on toxicity data no ecotoxicological effects are expected.

Section 13: Disposal

Dispose of in accordance with all applicable local and national regulations. Clean packaging materials can be recycled.

Section 14: Transport Information

Not regulated under DOT CFR 172.101 Data

Section 15: Regulatory Information

These products are regulated under the Federal Food Drug & Cosmetic Act and do not require an MSDS for hazard communication as stated in 29 CFR 1910.1200. This MSDS is supplied as an additional service SARA Title III: This product does not contain any chemicals subject to SARA Title III .

State Right To Know: This product does not contain any chemicals on the Massachusetts, Pennsylvania, New Jersey & California Right To Know hazardous substance lists.

Section 16: Other Information

NFPA Ratings per NFPA Codes:

Flammability: 0 Health: 0

Reactivity: 0 Special Hazards: 0

HMIS Ratings per HMIS Codes:

Flammability: 0 Health: 0

Reactivity: 0 Personal Protection: See Section 8

Safe n Simple LLC. is a registered Medical Devices manufacturer as designated by the FDA.

Disclaimer: This product is exempt from Safety Data Sheet regulations as the product is for consumer use. (Provided with this information by the compiling agencies): This information contained in this SDS is offered as a guide to the handling of this specific material. The information contained in this Safety Data Sheet (SDS) is offered as a guide to the use and handling of this material. It has been prepared in good faith by technically knowledgeable Personnel and it believed to be correct as of the effective date listed. All safety aspects of all Safe n Simple's products are thoroughly evaluated prior to commercialization Safe n Simple shall not be held liable for any damages, losses or injuries of any nature which may result from the use of or reliance upon any information contained in this SDS. Each individual should make a determination as to the suitability of the information for his or her particular purpose(s). Safe n Simple, LLC and the United States of America in no manner whatsoever, expressly or implied, warrants this information to be accurate and disclaims all liability for its use. Any person utilizing this document should seek competent professional advice to verify and assume responsibility for the suitability of this information to their particular situation.