Material Safety Data Sheet

Section 1 - Chemical Product and Company Identification

Product/Chemical Name: *AlgiSite* M Dressing*
Chemical Formula: N/A
CAS Number: N/A
Other Designations: None
General Use: Wound Dressing
Manufacturer: Smith & Nephew, Inc. 11775 Starkey Road Largo, FL 33773-4727 **Phone**: 1- 800-876-1261
Date Reviewed: December 8, 2003

Section 2 - Composition Information on Ingredients

Ingredient Name	CAS Number	% wt *or* % vol
Calcium Alginate	9005-35-0	Proprietary
Polysorbate 20	9005-64-5	Proprietary

Section 3 - Hazards Identification

☆ ☆ ☆ ☆ ☆ **Emergency Overview** ☆ ☆ ☆ ☆ ☆

HMIS	
H	1
F	0
R	0
PPE	0

Not classified as hazardous. Processing of any fibre can lead to fly (dust) formation.

Potential Health Effects

Symptoms and effects:
Exposure to high levels of fibre fly during processing may lead to irritation of the eyes, respiratory system and possibly skin.
Carcinogenicity: This material is not known to be carcinogenic.

Section 4 - First Aid Measures

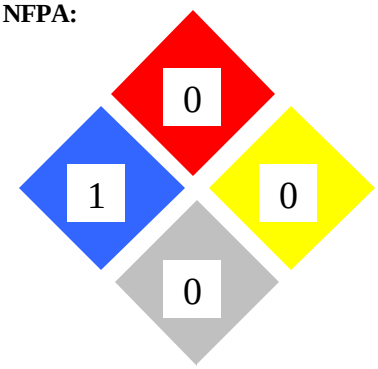
Inhalation: Remove effected person to fresh air. Seek medical attention if symptoms appear.
Eye Contact: Flush eyes with plenty of eye-wash solution or clean water, holding eye lids. If irritation persists seek medical attention.
Skin Contact: If irritation develops, wash with soap and water then seek medical attention.
Ingestion: No adverse effects expected due to ingestion.
After first aid, get appropriate in-plant, paramedic, or community medical support.

Advice to Physicians: Symptomatic and supportive treatment as indicated. Some individuals e.g. with asthma, may be intolerant to high concentrations of fibre 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.
Flash Point: Not applicable
Flash Point Method: Not applicable
LEL: Not known
UEL: Not known
Autoignition temperature: Not applicable
Flammability Classification: Not Flammable
Extinguishing Media: Water, foam, powder, carbon dioxide.
Unusual Fire or Explosion Hazards: None
Hazardous Combustion Products: The product decomposes on application of heat. The fumes should not be inhaled. Combustion products are similar to those of cellulosic fibres, i.e. mainly carbon monoxide, carbon dioxide and water.

NFPA:



Fire-Fighting Instructions: Do not release runoff from fire control methods to sewers or waterways.
Fire-Fighting Equipment: In event of a fire, wear full protective clothing and NIOSH approved self-contained breathing apparatus operated in the pressure demand or other positive pressure mode. Firefighters should wear whatever protective equipment is applicable for the material supporting combustion.

Section 6 - Accidental Release Measures

Spill /Leak Procedures:
Cleanup: Recover small quantities split material by hand. Sweep or vacuum up spills. Dispose in appropriate waste receptacle.
Regulatory Requirements: None known.

Section 7 - Handling and Storage

Handling Precautions: None
Storage Requirements: Store in a cool, dry place <77° F / 25°C.
Regulatory Requirements: None

Section 8 - Exposure Controls / Personal Protection

Engineering Controls: Controlling exposure to calcium alginate fibre as supplied should not be necessary but, in common with other fibres, exposure to dust (fly) resulting from processing should be controlled. Ensure good ventilation of the working area. In critical areas, extraction systems should be fitted. Cleaning should wherever possible be done using a vacuum. Guidance on the general principles of protection against dust is available in Note EH44, UK Health and Safety Executive publication (ISBN 0-7176-1435-2).
Ventilation: Ensure good ventilation of the working area.
Administrative Controls: None required.
Environmental Precautions: Calcium Alginate fibre is not expected to do any harm if released to the environment.
Exposure Limits: UK occupational exposure limit for 'total inhalable dust' is 10 mg/m^3, (8-hour time weighted average) and for 'respirable dust' is 4 mg/m^3 (8-hour time weighted average).
Respiratory Protection: Wear suitable respiratory protection when cleaning up dusts.
Protective Clothing/Equipment: Wear suitable eye/face protection when opening material secured with straps or wires. Wear suitable protective gloves when opening material secured with straps or wires. No personal precautions thought necessary in dealing with split fibre.
Contaminated Equipment: Regular cleaning of processing equipment is recommended in order to avoid accumulations of fibre fly (dust).
Comments: Never eat, drink, or smoke in work areas. Practice good personal hygiene after using this material, especially before eating, drinking, smoking, using the toilet, or applying cosmetics.

Section 9 - Physical and Chemical Properties

Physical State: Solid
Appearance and Odor: Off-white, odorless non-woven fabric.
Water Solubility: Insoluble
Boiling Point: Not applicable
Odor Threshold: Not known
Viscosity: Not applicable
Vapor Pressure: N/A
Vapor Pressure Density: Not applicable
Partition coefficient n-octanol/water: Not applicable
Other Solubilities: Will gel or dissolve in aqueous solutions containing sodium or certain other ions.
Melting Point / range: Fibre will decompose when in contact with flames.
Density: 1.75g/cm^2 (individual fibers).
pH: Neutral (does not impart significant acidity or alkalinity).

Section 10 - Stability and Reactivity

Stability: Stable.
Polymerization: Hazardous polymerization will not occur.
Hazardous Decomposition Products: None known.
Conditions to Avoid: Stable under normal conditions of use. Note that the fibre will gel or dissolve in aqueous solutions containing soidium, or certain other ions.

Section 11 - Toxicological Information

The results of haemolysis, cytotoxicity, acute systemic toxicity and skin irritation studies opposite, carried out on sterilised product, do not provide any evidence that the product is toxic. Likewise, the product does not cause contact sensitisation on repeated application.

Haemolysis: US National Formulary XIV
Skin irritation: ISO 10993 – Part 10
Cytoxicity: ISO 10993 – Part 5
Contact sensitisation: ISO 10993 – Part 10
Acute systemic toxicity: ISO 10993 – Part 11

The ability of the product to support healing of granulation tissue in the pig [(1)] and the widespread use of aliginc acid and its salts in antacid preparations for man, provide evidence for the lack of toxicity of alginate products in general when applied to the mucous membranes. A long history of use of calcium alginate products in general for wound treatment has established their suitability for this application. Calcium alginate, as a general material, is listed in the EEC as a permitted food additive (E404) and in the USA is approved as a food additive by the FDA (21.CFR.184.1187). The effects of any changes to the physical or chemical form of the product, on processing, should be assessed.

Reference

(1) S E Barnett & S J Varley, Ann. R. Coll. Surg. (Eng.) 1987, 69, 153-5.

Section 12 - Ecological Information

This preparation has not been tested.

Section 13 - Disposal Considerations

Disposal: Contact your supplier or a licensed contractor for detailed recommendations. Follow applicable Federal, state, and local regulations pertaining to the disposal of non-hazardous waste. Recover as much product as possible from packaging. The clean packaging can then be recycled.

Section 14 - Transport Information

DOT Transportation Data (49 CFR 172.101):
Not Regulated

Not classified as dangerous for conveyance under the UK Carriage of Dangerous Goods (Classification, Packaging and Labeling) and Use of Transportable Pressure Receptacles Regulations (1996) or under the European agreement concerning international carriage of goods by road (ADR) or rail (RID), or the international agreement for carriage by sea (IMDG) or air (ICAO/IATA).

Section - 15 Regulatory Information

This safety data sheet and the resulting chemical classification is written in accordance with UK Chemicals (Hazard Information and Packaging for Supply) (Amendment)(CHIP) Regulations 1997, which in turn enact European Directive 93/112/EEC (Amendment to the Safety Data Sheet Directive) and Article 10 of Directive 88/379/EEC (the Dangerous Preparations Directive).

EC classification: Not classified as dangerous.
Risk phrases: None
Safety phrases: None
EPA Regulations: None known for normal use
OSHA Regulations: None known for normal use
State Regulations: May vary from state to state

Section 16 - Other Information

Additional Hazard Rating Systems: None Known

Training and related advice: This document contains important information to ensure the safe storage, handling and use of this product. The information in this document should be brought to the attention of the person in your organization responsible for advising on safety matters.

Technical information provided in the Material Safety Data Sheet should not be used other than for the purposes of assessing hazards for safety, health and environment. It should not be used as a technical specification for engineering calculations.