SAFETY DATA SHEET (SDS)

According to 1907/2006/EC, Article 31



May be used to comply with OSHA's Hazard Communication Standard, 29 CFR 1910.1200. Standard must be consulted for specific requirements.

Section I – Identification of the substance/mixture and of the company/undertaking					
IDENTITY (As Used on Label and List) DermaGinate/Ag TM ALGINATE DRESSING with ANTIBACTERIAL SILVER	Note: Blank spaces are not permitted. If any item is not applicable, or no information is available, the space must be marked to indicate that.				
Manufacturer's Name	Emergency Telephone Number				
DermaRite Industries	(973) 569-9000				
Address (Number, Street, City, State, and ZIP Code)	Telephone Number for Information				
7777 West Side Avenue, North Bergen, NJ 070473	(973) 569-9000				

Section II – Hazardous identification

List all hazards regarding the material

Maybe cause eyes irritation due to mechanical abrasion. Ingestion may cause discomfort in mouth, throat and stomach.

List all required label requirement

Label of pouch should contain product name, specification, symbol of "do not reuse", "do not use when broken or damage", "sterile", "see IFU", warning, manufacturer, EXP, LOT and MFD.

IFU should contain product name, description, indications, contraindications, product information, instruction for use, warnings, adverse reactions, storage, shelf life, manufacturer.

Recommended use and restriction of use

Rx: Intended for moderately to heavily exuding partial to full thickness wounds, including: trauma wounds, pressure ulcers, diabetic ulcers, leg ulcers, graft and donor sites, post-operative.

OTC: Do not use on patients with known sensitivity to silver, or third-degree burns.

Section III – Composition/Information on Ingredients				
Other Limits Hazardous Components (Specific Chemical Identity; Common Name(s) %(optional)	OSHA	PEL	ACGIH TI	LV Recommended
Basic material: calcium alginate: >99.9%				
Antibacterial agent: silver particle: 40-60ug/100cm ²				
Coupling agent: silicon compound: 0.1-0.2%				

Section IV – First aid measures

Signs and Symptoms of Exposure and Required Treatments

Eyes: Immediately flood the eye with plenty of water for at least 15 minutes, holding the eye open. Obtain medical attention if soreness or redness persists.

Skin: If skin irritation develops, or other symptoms occur, discontinue use. Wash skin thoroughly with normal saline.

Seek medical attention if symptoms persist.

Ingestion: Obtain medical attention immediately.

Inhalation: Seek medical attention if symptoms persist.

Advice to Physicians: Treat symptomatically.

Section V – Fire Fighting Measures							
Flash Point (Method Used) N/A		Flammable Limits None known	LEL N/A	_	IEL I/A		
Extinguishing Media	er spray, dry chemical or ca	rhon dioxide					
Use water spray, dry chemical or carbon dioxide. Special Fire Fighting Procedures							
Wear full protective clothing and self-contained breathing apparatus. Unusual Fire and Explosion Hazards N/A							
Onusual Fire and Explosion Hazards	WA.						
Section VI – Accidental re	lease measures						
Steps to Be Taken in Case Material Is Rel No step should be taken.	eased or Spilled						
Respiratory Protection (Specify Type) N.A							
Ventilation	Local Exhaust		Special	NI/A			
N/A	Mechanical (General	N/A	Other	N/A			
Protective Gloves		N/A Eye Protection	N/A				
N/A		N/A					
Other Protective Clothing or Equipment	Nor	mal work clothes.					
Work/Hygienic Practices N/A							
Section VII- Handling and	Storage						
Precautions to Be Taken in Handling and No precaution should							
Incompatibilities							
Keep away from moist	ture, heat and sources of i	inition.					
Coation VIII Evenaura ad	ntrolo/noroonal protoc	tion					
Section VIII – Exposure co		tion					
N/A							
Threshold limit values (TLVs) N/A							
Appropriate engineering controls No specific measure necessar	·V.						
Personal protective equipment (PPE)	, .						
No equipment to be needed.							
Section IV Physical and	chamical proportios						
Section IX – Physical and	chemical properties	Specific Gravity (F	H ₂ O = 1)		N/A		
Boiling Point	N/A	Melting Point	<u> </u>		N/A		
Vapor Density (AIR = 1) At 20°C	N/A	Evaporation Rate (Butyl Acetate = 1)		N/A		
Solubility in Water Not soluble.		pH 5.0-8.0	,				
Appearance and Odor							
White or light-yellow non-woven fill Section X – Stability and F							
Stability	Unstable	Conditions to Avoid					
•	Stable	Moisture, heat and	sources of ignition	1			
Incompatibility (Materials to Avoid)	√						
Avoid water and others liquid, sunlight. Hazardous Decomposition or Byproducts							
Hazardous Polymerization	Will not occur May Occur						
·	Will Not Occur √						
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Section XI – Toxicological Information						
Route(s) of Entry:	Skin					
Health Hazards (Acute and Chronic)						
	Cytotoxicity, irritation, sensitization o	or acute toxicity.				
Carcinogencity:	NTP?	IARC Monographs?				
OSHA Regulated?	N/A					
Signs and Symptoms of Exposure N						
Medical Conditions						
Generally Aggravated by Exposure	N/A					
Emergency and first aid procedures						
N/A						
Section XII – Ecological	Information					
Not applicable						
Section XIII - Disposal (Consideration					
Waste Disposal Method	with all applicable local and patienal re	aulations				
Dispose of in accordance w	vith all applicable local and national re	guiations.				
Section XIV- Transport	Information					
	ations to properly classify your shipme	ent.				
Section XV- Regulatory	Information					
Not applicable						
Section XVI – Other Info	ormation					
Not applicable						
Date Prepared 01/29/2015						
Signature of Preparer (optional)						

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