

March 27, 2020

URGENT DRUG/COSMETIC RECALL OF DERMATONE SUNSCREEN LOTION SPF 50 AND SPF 30 DUE TO MICROBIOLOGICAL GROWTH

Dear Customer,

The purpose of this letter is to inform you of a product recall by Dermatone and Filltech, USA involving:

Dermatone Sunscreen Lotion SPF 30	Dermatone Sunscreen Lotion SPF 50
Lot number 22J19 exp. 07/21, 1.5 Oz. Tottle	Lot number 05J19 Exp. 07/21, 1.5 Oz. Tottle and 2 Oz. Tube
	Lot number 05J19 Exp. 07/21, 1.5 Oz. Tottle and 2 Oz. Tube
	Lot number 44L19 Exp. 09/21, 4 Oz. Tube

See enclosed product label for ease in identifying the product at retail level.

This recall has been identified due to microbiological growth (yeast) detected in one lot. Use of this product may cause a possible health hazard if used on broken skin.

We began shipping this product in July 2019. We recommend that you immediately examine your inventory and quarantine the product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

Customers and users must discard the product at once. Wholesale and retail please return to FillTech USA for destruction.

Return Address: FillTech USA

380 Palmer Road, Rockwell, NC 28138

Please complete and return the included form as soon as possible. Email the form to Jan Ivey at JIVEY@BEAUMONTPRODUCTS.COM.

This recall should be carried out to the consumer level. Your assistance is appreciated and necessary to prevent consumer illness.

If you have any questions, call Jan Ivey at 678-931-6217. Hours of operation are 9 AM to 5 PM Eastern Time.

This recall is being made with the knowledge of the Food and Drug Administration.

Sincerely,

Jan Juey

Jan Ivey

V.P. of Research and Development

Beaumont Products, Inc.

Encl: Recall Response Form



REPLY FORM - RESPONSE REQUIRED

PLEASE EMAIL A COMPLETED RESPONSE FORM TO <u>JIVEY@BEAUMONTPRODUCTS.COM</u>

REQUIRED INFORMATION:					
Business Name					
Phone Number					
Address					
City/State/Zip					
Email address					
Completed by: Printed Name/S	Signature			Date	<u> </u>
Please check ALL appropriate I have read and under Indicate disposition o Returned Destroyed Quarantined DISPOSITION:	rstand the reca		s provided in th	ne letter.	
PRODUCT NAME	SIZE	LOT NUMBER	QUANTITY (TUBES)	DISPOSITION METHOD	DATE
Dermatone Sunscreen Lotion SPF	30 1.5 Oz.	22J19	(10020)		
Dermatone Sunscreen Lotion SPF	50 1.5 Oz.	05J19			
Dermatone Sunscreen Lotion SPF	50 2 Oz.	05J19			
Dermatone Sunscreen Lotion SPF	50 2 Oz.	43L19			
Dermatone Sunscreen Lotion SPF	50 4 Oz.	43L19			
Dermatone Sunscreen Lotion SPF	50 4 Oz.	44L19			
Any adverse events associated If yes, please explain:				No □	

Return product to: FillTech USA 380 Palmer Road, Rockwell, NC 28138

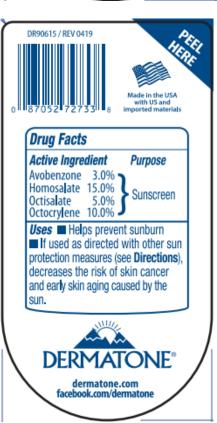
Email this form to: JIVEY@BEAUMONTPRODUCTS.COM













Drug Facts

caused by the sun.

Warnings - For external use only. Do not use on damaged or broken skin. • When using this product keep out of eyes. Rinse with water to remove. • Stop use and ask a doctor if rash occurs. • Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

- Apply liberally 15 minutes before sun exposure. Reapply after 80 minutes of swimming or sweating, immediately after towel drying and at least every 2 hours
- protection measures including: limit time in the sun, especially from 10 a.m. 2 p.m. wear long-sleeve shirts, pants, hats, and sunglasses.
 Children under 6 months: Ask a doctor

heat and direct sun.

Inactive ingredients Water, Glyceryl Stearate, Butyloctyl
Salicylate, VP/Eicosene Copolymer, Leuconostoc/Radish
Root Ferment Filtrate, Ethylhexyl Methoxycrylene,
Acrylates Copolymer, Glycerin, Stearic Acid, Behernyl
Alcohol, Lecithin, Myristyl/Lauryl/Cetyl Alcohol, Palmitic
Acid, Taploca Starch (and) Polymethylsilsesquioxane,
PEG-100 Stearate, Acrylates/Steareth-20 Methacrylate
Copolymer, Xanthan Gum, Polysorbate 80, Disodium
EFDTA.



Fragrance Free **Water Resistant** (80 Minutes) **Broad Spectrum SPF 50** Moisturizing **Non-Greasy** 2 FL. OZ. (59mL)



Drug Facts Active Ingredient Purpose Avobenzone 3.0% Iomosalate 15.0% Sunscreen Octisalate 5.0% Octocrylene 10.0%

Uses - Helps prevent sunburn - If used as directed with other sun protection measur (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

by the sun.

Warnings - For external use only.

Do not use on damaged or broken skin. When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash occurs. • Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure.

- limit time in the sun, especially from 10 a.m. 2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses
 Children under 6 months: Ask a doctor

Distributed By: umont Products, Inc. nnesaw, GA 30144

stions or Comments 1-800-451-7096





