



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:

<b>Dermatone Sunscreen Lotion SPF 30</b>	<b>Dermatone Sunscreen Lotion SPF 50</b>
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](mailto: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 Ivey*

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 [JIVEY@BEAUMONTPRODUCTS.COM](mailto:JIVEY@BEAUMONTPRODUCTS.COM)**

**REQUIRED INFORMATION:**

Business Name	
Phone Number	
Address	
City/State/Zip	
Email address	

**Completed by: Printed Name/Signature**

**Date**

Please check ALL appropriate boxes.

- I have read and understand the recall instructions provided in the letter.
- Indicate disposition of recalled product
  - Returned
  - Destroyed
  - Quarantined

**DISPOSITION:**

PRODUCT NAME	SIZE	LOT NUMBER	QUANTITY (TUBES)	DISPOSITION METHOD	DATE
Dermatone Sunscreen Lotion SPF 30	1.5 Oz.	22J19			
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 with recalled/failed product? Yes  No

If yes, please explain: \_\_\_\_\_

Please check the appropriate box(es) to describe the nature of your business:

- Wholesaler/distributor       Grocery       Other: \_\_\_\_\_
- Pharmacy/Retail       Retailer

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

Email this form to: [JIVEY@BEAUMONTPRODUCTS.COM](mailto:JIVEY@BEAUMONTPRODUCTS.COM)



FRAGRANCE FREE  
**SPF 30**

**US**  
SKI & SNOWBOARD  
OFFICIAL SUNSCREEN SPONSOR

**DERMATONE**  
Sunscreen Lotion

FRAGRANCE FREE  
Water Resistant (80 Minutes)  
Broad Spectrum SPF 30  
Moisturizing  
Non-Greasy

1.5 fl. oz. (44mL)

DR900370\_REV 0419

DR90340 / REV 0519

0 209081 42269 8

MADE IN THE USA  
with US and imported materials

**PEEL HERE**

**Drug Facts**

Active Ingredient	Purpose
Avobenzone 3.0%	Sunscreen
Homosalate 10.0%	
Octisalate 5.0%	
Octocrylene 10.0%	

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

**DERMATONE**  
dermatone.com  
facebook.com/dermatone

FRAGRANCE FREE  
**SPF 50**

**US**  
SKI & SNOWBOARD  
OFFICIAL SUNSCREEN SPONSOR

**DERMATONE**  
Sunscreen Lotion

FRAGRANCE FREE  
Water Resistant (80 Minutes)  
Broad Spectrum SPF 50  
Moisturizing  
Non-Greasy

1.5 fl. oz. (44mL)

DR90605\_REV 0419

DR90615 / REV 0419

0 87052 72733 8

MADE IN THE USA  
with US and imported materials

**PEEL HERE**

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Active Ingredient	Purpose
Avobenzone 3.0%	Sunscreen
Homosalate 15.0%	
Octisalate 5.0%	
Octocrylene 10.0%	

**Uses** ■ Helps prevent sunburn  
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Homosalate 15.0%	
Octisalate 5.0%	
Octocrylene 10.0%	



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

**Directions**

- 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
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun 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

**Other Information** - Protect this product from excessive 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, Behenyl Alcohol, Lecithin, Myristyl/Lauryl/Cetyl Alcohol, Palmitic Acid, Tapioca Starch (and) Polymethylsilsequioxane, PEG-100 Stearate, Acrylates/Steareth-20 Methacrylate Copolymer, Xanthan Gum, Polysorbate 80, Disodium EDTA

Distributed By:  
Beaumont Products, Inc.  
Kennesaw, GA 30144  
**Questions or Comments**  
1-800-451-7096  
dermatone.com  
facebook.com/dermatone



Fragrance Free  
Water Resistant  
(80 Minutes)  
Broad Spectrum SPF 50  
Moisturizing  
Non-Greasy

2 FL. OZ. (59mL)



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(80 Minutes)  
Broad Spectrum SPF 50  
Moisturizing  
Non-Greasy

4 FL. OZ. (118mL)



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Water Resistant  
(80 Minutes)  
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4 FL. OZ. (118mL)