

DermaRite Expands Voluntary Nationwide Recall in 2025 Due to Burkholderia Cepacia Contamination

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DermaRite Industries Expands Voluntary Nationwide Recall Due to Potential Burkholderia cepacia Contamination

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FOR IMMEDIATE RELEASE

DermaRite Industries, LLC is expanding the voluntary recall initiated on July 16, due to potential microbial contamination identified as Burkholderia cepacia complex. Out of an abundance of caution the voluntary recall has expanded to include additional products and lots, which can be found in the table below. Please see [DermaRite.com](https://dermarite.com) for the original recall notice.

Risk Statement: Burkholderia cepacia complex in these products may result in serious and life-threatening infections if the products are used by immunosuppressed individuals or by people attending to immunosuppressed individuals. For healthy individuals with minor skin lesions, the use of the product may result in local infections, whereas in immunocompromised individuals the infection could spread into the blood stream, potentially leading to life-threatening sepsis.

The products included in this expanded voluntary recall include:

3-N-1 is a thick foaming, rinse-free, body wash, shampoo, and perineal cleanser. Enriched with Aloe Vera, it soothes and moisturizes fragile skin as it cleans.

4-N-1 is a no rinse wash cream intended to temporarily protect and help relieve chafed or cracked skin

Clean-N-Free is a mild, rinse-free, body wash, shampoo, and perineal cleanser that cleans and refreshes without water. Perfect for bed-bound residents and patients.

DermaCerin is a skin protectant moisturizing cream indicated to temporarily protect and help relieve dry, chapped, or cracked skin. It also helps protect skin from the drying effects of wind and cold weather.

DemaDaily is a moisturizing lotion that soothes dry, sensitive skin.

DermaFungal is an OTC antifungal cream intended for the treatment and prevention of most athlete's foot, jock itch, and ringworm. It relieves itching, scaling, cracking, and discomfort associated with these conditions.

DermaKleen is an OTC healthcare antiseptic lotion soap with Vitamin E indicated for handwashing to decrease bacteria on the skin.

DemaKlenz is a mild, non-irritating wound cleanser. Gentle on sensitive wounds. Effectively removes debris and dead tissue. No rinsing necessary. Reduces Odor

DermaMed is an OTC skin protectant intended to dry the oozing and weeping of poison ivy, oak, or sumac, or other skin irritations.

DermaRain is an extra mild bodywash and shampoo that is pH balanced and dye free. Suitable for all skin types.

DermaSarra is an OTC external analgesic indicated for temporary relief of itching associated with minor skin irritations due to dry skin, insect bites, detergents, or sunburn.

DermaSyn is a hydrogel wound dressing that provides and helps maintain a moist wound environment, facilitating autolytic debridement.

DermaVantage moisturizing lotion soothes and moisturizes dry, sensitive skin.

DermaVera is a full body cleanser suitable for skin and hair. Moisturizes with shea butter.

Gel Rite is an OTC instant gel hand sanitizer with vitamin E used to decrease bacteria on the skin. It is recommended for repeated use.

Hand E Foam is an OTC foaming hand sanitizer with vitamin E used for handwashing to decrease bacteria on the skin. It is recommended for repeated use.

KleenFoam is an OTC antimicrobial foam soap with Aloe Vera indicated for handwashing to decrease bacteria on the skin after changing diapers, after assisting ill people, or before contact with a person under medical care or treatment.

Lantiseptic is an OTC skin protectant indicated to temporarily protect minor cuts, scrapes and burns. It helps prevent and temporarily protect chapped or cracked skin.

LubriSilk is a lotion that soothes, lubricates, and softens rough, dry skin. Use on

hands, face, legs, elbows and heels for healthy, moisturized skin.

PeriFresh is a mild cleanser spray designed for incontinence use. Perifresh's non-drying formula nourishes your skin with aloe vera, leaving your skin clean and healthy. More convenient than conventional soap and water, it cleans and deodorizes with a light fruit fragrance.

PeriGiene is an OTC antiseptic cleanser indicated for use in the perineal area.

PeriGuard is an OTC skin protectant indicated to help relieve and prevent rashes and irritation due to wetness from incontinence. It also protects chafed skin due to irritation and helps seal out wetness.

Renew Hair and Body Wash is formulated to nourish and clean from head to toe. The rich, creamy lather soothes and softens skin and hair with a blend of beneficial vitamins and shea butter. Fresh tropical coconut scent.

Renew Dimethicone is an OTC skin protectant indicated to help treat and prevent diaper rash, protect minor skin irritations associated with diaper rash, and helps seal out wetness.

Renew Full Body Wash & Shampoo is a mildly formulated bodywash & shampoo, suitable for hands, body, hair, and perineal care. This non-drying formula nourishes your skin with aloe vera, leaving your skin clean and healthy. Light fruit fragrance.

Renew Periprotect is an OTC skin protectant indicated to help treat and prevent diaper rash, protect minor skin irritation associated with diaper rash, and helps seal out wetness.

Renew Skin Repair is an OTC Skin cream indicated to temporarily protect and help relieve chapped or cracked skin. It is beneficial for face, hands, body and legs.

San-E-Foam is a foaming hand sanitizer with vitamin E use for handwashing to decrease bacteria on the skin. Is recommended for repeated use.

TotalBath is a head-to-toe bodywash and shampoo. Enriched with vitamin E, it moisturizes as it cleans for soft, healthy skin and hair.

TotalFoam is a mildly formulated bodywash & shampoo, suitable for hands, body, hair, and perineal care. TotalFoam's non-drying formula nourishes your skin with aloe vera, leaving your skin clean and healthy. Light fruit fragrance.

UltraSure is an OTC anti-perspirant & deodorant indicated to reduce underarm

wetness.

WhirlBath is a head-to-toe bodywash and shampoo, specially formulated with mild cleansers and conditioners for whirlpool and tub use.

The recalled products were distributed nationwide in the United States and in Puerto Rico.

DermaRite has notified its distributors and customers by e-mail to immediately examine available inventory and destroy all affected products in accordance with each facility’s process.

Consumers with questions regarding this recall can call Sedgwick at 888-943-5190 Monday through Friday, 8:00 am – 5:00 pm EST or email dermarite5186@sedgwick.com

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product or have questions about whether the product was used in their health care facility.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA’s MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Recalled Product Information:

Product Description	Item No.	All lots on or before Expiry date
Product Description Item No. All lots on or before Expiry date 3-N-1 Cleansing Foam 7.5 oz. , 12/case	00190	08/2027

4-N-1 Wash Cream 4oz ,24/case	00208	08/2027	x
Clean-N-Free Bottle 7.5oz., 48/case	00193	08/2027	x
DermaCerin (lg. jar) 16oz., 24/case	00176	08/2027	x
DermaCerin tubes 3.75oz., 24/case	00174	08/2027	x
DermaDaily lotion 4oz., 96/case	00124	08/2027	x
DermaDaily lotion 7.5oz., 48/case	DL	00128	08/2027 ✓
DermaDaily lotion 1000 ml. bag-n-box, 10/case 00122BB	00234	08/2027	
08/2027 DermaFungal 3.75oz. tube, 24/case			x
DermaFungal 5g packets, 144/box	00233	08/2027	x
DermaKleen 1000ml. bag-n-box, 10/case 0092BB 08/2027	0098	08/2027	
DermaKleen 7.5oz., 24/case			x
DermaKleen 800ml. bag-n-box, 12/case 0090BB 08/2027	00249	08/2027	
DermaKlenz 8oz., 24/case	DL		✓
DermaKlenz Spray 4oz., 12/case	00243	08/2027	x
DermaMed Ointment 3.75oz. tube, 24/case	00214	08/2027	x
DermaRain 16oz., 12/case	0060	08/2027	x
DermaRain 7.5oz., 48/case	0056	08/2027	x
DermaRain 800ml. bag-n-box, 12/case 0049BB 08/2027	00188	08/2027	
DermaSarra 7.5oz, 24/case			x
DermaSyn 3oz. tube, 24/case	00247	08/2027	x
DermaVantage 2oz. tube, 72/case	00142	08/2027	x
DermaVantage lotion 7.5oz, 48/case	00148	08/2027	x
DermaVantage lotion 1000ml. bag-n-box, 10/case	0012	08/2027	
00149BB 08/202 DermaVera 800ml. bag-n-box, 12/case			
0013BB 08/2027 DermaVera 1000ml. bag-n-box, 10/case			
0014BB 08/2027 DermaVera 4oz, 96/case			x
DermaVera 7.5oz. bottle, 48/case	0016	08/2027	x

DermaVera Gallon, 4/case	0017	08/2027
GelRite 1000ml, 10/case 00110BB 08/2027 GelRite 16oz., 12/case	00106	08/2027
GelRite 4oz., 24/case	00104	08/2027
GelRite 800ml., 12/case 00100BB 08/2027 Hand-E-Foam 1000ml., 6/case 00109F 08/2027 Hand-E-Foam 8oz., 12/case	00108	08/2027
KleenFoam 1000ml., 6/case 0093F 08/2027 Lantiseptic Daily Care Skin Therapy 14oz Jar Case/12 LS0710 08/2027 Lantiseptic Dry Skin Therapy 4oz Tube Case/12 LS0410 08/2027 Lantiseptic Dry Skin Therapy 5g Packets 144/Box LS0404 08/2027 Lantiseptic Skin Protectant 4.5oz Jar Case/24 LS0310 08/2027 Lantiseptic Skin Protectant 12oz Jar Case/12 LS0311 08/2027 Lantiseptic Skin Protectant 14.2g Packets Case/144 LS0305 08/2027 Lantiseptic Skin Protectant 4oz Tube Case/12 LS0308 08/2027 Lantiseptic Skin Protectant 5g Packets Case/288 LS0304 08/2027 LubriSilk lotion, 16oz 12/case 00166P 08/2027 McKesson Skin Protectant 4oz Tube Case/24 LS4615 08/2027 McKesson Skin Protectant 5g Packets Case/288 LS4613 08/2027 PeriFresh (Perineal Cleanser) 7.5oz., 48/case	00199	08/2027
PeriFresh (Perineal Cleanser) gallons w/fragrance, 4/case	00196	08/2027
PeriGiene 7.5oz., 48/case	00198	08/2027
PeriGuard 3.5oz tube, 24/case	00204	08/2027
PeriGuard 7oz tubes, 48/case	00205	08/2027
PeriGuard ointment packets 5g, 144/box	00200	08/2027
Renew 8oz shampoo/body wash, 24/case	00425	08/2027
Renew Dimethicone Skin Protectant packets 5g, 144/box	00411	08/2027
Renew Full-Body foaming cleanser 8oz, 12/case	00420	08/2027
Renew PeriProtect 4oz tube 12/case	00435	08/2027

Renew Skin Protectant w/ dimethicone, 12/case	00410	08/2027
Renew Skin Repair 4oz tube, 12/case	00405	08/2027
Renew Skin Repair 5g packets, 144/box	00400	08/2027
Renew Skin Repair 800mL, 12/case 00407BB 08/2027	0028	08/2027
San-E-Foam 1000ml., 6/case 00107F 08/2027 TotalBath		
1000ml. bag-n-box, 10/case 0025BB 08/2027 TotalBath		
7.5oz., 48/case		
TotalBath 800ml. bag-n-box, 12/case 0020BB 08/2027	0031	08/2027
TotalBath gallon, 4/case		
TotalFoam 1000ml., 6/case 0026F 08/2027 UltraSure	00266	08/2027
Deodorant Pump Spray 4 oz., 24/case		
Whirlbath Balance gallons,4/case	00225	08/2027

Labels of affected products can be viewed [here](#).

◀ DermaRite Industries Issues Voluntary Nationwide Recall of DermaKleen, Dermasarra, Kleenfoam, and Perigiene Products Due to Burkholderia cepacia Contamination.

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