

NANOCARE MOISTURIZING SUNSCREEN SPF 50- benzophenone, avobenzone, octisalate, homosalate, and octocrylene lotion
Deramzone Solutions, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

nanocare for skin
Moisturizing Sunscreen SPF 50

Drug Facts

Active ingredients

Benzophenone-3 6.0%
Butyl Methoxydibenzoylmethane 3.0%
Ethylhexyl Salicylate 5.0%
Homosalate 10.0%
Octocrylene 8.0%

Purpose

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
 - 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

Inactive ingredients

USP water, potassium cetyl phosphate, alcohol, dicaprylyl maleate, sorbitol, bis-stearyl/ethylenediamine/neopentyl glycol/stearyl hydrogenated dimmer dilinoleate copolymer, cetyl alcohol, lecithin, aloe barbadensis leaf juice, carbomer, tocopheryl acetate, methylparaben, propylparaben, triethanolamine

Manufactured by:

Dermazone Solutions, Inc.

2440 30th Avenue North St. Petersburg, FL 33713 USA

Distributed by: Universal Sales & Marketing, Inc.

PRINCIPAL DISPLAY PANEL - 88 mL Tube Carton

nanocare
for skin

Moisturizing Sunscreen

SPF 50

Broad Spectrum Protection

WATER RESISTANT
(80 MINUTES)

Clinical Skin Care
with Lyphazome[®] Technology

3.0 FL OZ (88 mL)

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Distributed by: Universal Sales & Marketing, Inc.
1-855-USA-1212

U.S. Patent App. Nos. 60/755,171 |
11/644,281 | 12/772,838 | 06/851,496.7
EU Patent App No. PCT/US06/48770

Made in the USA

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nanocare
for skin

Moisturizing Sunscreen
SPF 50

Broad Spectrum Protection

WATER RESISTANT
(80 MINUTES)

Clinical Skin Care
with Lyphazome® Technology

3.0 FL OZ (88 mL)

DESCRIPTION:

This lightweight, moisturizing sunscreen lotion provides durable protection from the harmful effects of UVA and UVB rays. Long-lasting benefits for all skin types, including sensitive skin include:

- Time-released all-natural Lyphazome nanotechnology
- Oil free, PABA free, and fragrance free
- Broad spectrum protection
- Water resistant for 80 minutes
- Safe for all skin types

BENEFITS:

- Reduces the risk of skin cancer and early skin aging, as well as helps prevent sunburn, if used as directed with other sun protection measures

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NANOCARE MOISTURIZING SUNSCREEN SPF 50

benzophenone, avobenzone, octisalate, homosalate, and octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58466-033
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzophenone (UNII: 701M4TTV9O) (Benzophenone - UNII:701M4TTV9O)	Benzophenone	60 mg in 1 mL
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	30 mg in 1 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	50 mg in 1 mL
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	100 mg in 1 mL
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	80 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
potassium cetyl phosphate (UNII: 03KCY6P7UT)	
alcohol (UNII: 3K9958V90M)	
dioctyl maleate (UNII: OD88G8439L)	
sorbitol (UNII: 506T60A25R)	
cetyl alcohol (UNII: 936JST6JCN)	
aloe vera leaf (UNII: ZY81Z83H0X)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
trolamine (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58466-033-33	1 in 1 CARTON		
1		88 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph final	part352	10/15/2012	

Labeler - Deramzone Solutions, Inc. (136116865)

Establishment

Name	Address	ID/FEI	Business Operations
Deramzone Solutions, Inc.		136116865	MANUFACTURE(58466-033)

Revised: 12/2012

Deramzone Solutions, Inc.