

DERMA SOLEIL NATURAL SUNBLOCK SPF 45- octocrylene, octyl methoxycinnamate, octyl salicylate, oxybenzone lotion

Biological Health Group

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.

DERMA SOLEIL NATURAL SUNBLOCK SPF 45

Octocrylene 7%

Octyl Methoxycinnamate 7.5%,

Octyl Salicylate 5%,

Oxybenzone 6%

Sunscreen

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.

For external use only.

Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs.

When using this product keep out of eyes. Rinse with water to remove.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

• Apply liberally 15 minutes before sun exposure • Reapply: • after 40 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 value 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-sleeved shirts, pants, hats, and sunglasses • children under 6 months of age: ask a doctor

Aloe Vera Gel, C12-15 Alkyl Benzoate, Aqua and Glycerin and Sodium Levulinate and Sodium Anisate, Fragrance, Acrylates/C10-30 Alkyl Acrylates Crosspolymer, Aminomethyl Propanol, Carbomer, Titanium Dioxide, Hydroxypropyl Methylcellulose, Tetrasodium EDTA, Evening Primrose Oil, Avocado Oil, Jojoba Oil, Grape Seed Oil, Blue Chamomile Oil, Calendula Oil, Hydrolyzed Wheat Protein, Retinyl Palmitate, Ascorbic Acid, Tocopherol Acetate.

Derma

Soleil

Natural Sunblock

**Broad
Spectrum
SPF 45+**



*Moisturizing with
Vitamins A, C, E & Aloe*

**UVA / UVB Protection
Water Resistant (40 minutes)
PABA Free**

For All Skin Types

e120mL Net 4.0 fl. oz

Sunblock Broad Spectrum SPF 45+

Drugs Facts

Active Ingredient	Purpose
Octocrylene 7 %	Sunscreen
Octyl Methoxycinnamate 7.5 %	Sunscreen
Octyl Salicylate 5 %	Sunscreen
Oxybenzone 6 %	Sunscreen

Uses

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Inactive Ingredients: Aloe Vera Gel, C12-15 Alkyl Benzoate, Aqua and Glycerin and Sodium Levulinate and Sodium Anisate, Fragrance, Acrylates/C10-30 Alkyl Acrylates Crosspolymer, Aminomethyl Propanol, Carbomer, Titanium Dioxide, Hydroxypropyl Methylcellulose, Tetrasodium EDTA, Evening Primrose Oil, Avocado Oil, Jojoba Oil, Grape Seed Oil, Blue Chamomile Oil, Calendula Oil, Hydrolyzed Wheat Protein, Retinyl Palmitate, Ascorbic Acid, Tocopherol Acetate.

Questions? Call toll-free from US & CA +1-844-881-2882 or visit www.derma-med.com.

Distributed in the US by:
Biological Health Group



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Made in Canada

Derma
Soleil

Natural Sunblock

Broad Spectrum SPF 45+

80% natural

Moisturizing with Vitamins A, C, E & Aloe

UVA / UVB Protection
Water Resistant (40 minutes)
PABA Free

For All Skin Types

e240mL Net 8.0 fl. oz

**Natural Sunblock
Broad Spectrum SPF 45+**

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69711-907
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	6 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
HYDROLYZED WHEAT PROTEIN (ENZYMATIC, 3000 MW) (UNII: J2S07SB0YL)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
GLYCERIN (UNII: PDC6A3C0OX)	
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MMB07FC)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	
EDETATE SODIUM (UNII: MPLJ8420LU)	
JOJOBA OIL (UNII: 724GKU717M)	
SODIUM LEVULINATE (UNII: VK44E1MQU8)	
SODIUM ANISATE (UNII: F9WFJ28MV9)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
WATER (UNII: 059QF0KO0R)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69711-907-01	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/24/2020	
2	NDC:69711-907-02	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/24/2020	

Establishment

Name	Address	ID/FEI	Business Operations
Derma Soleil		202617023	manufacture(69711-907)

Revised: 2/2020

Biological Health Group