

**DERMA SOLEIL NATURAL AGE-FREE FACIAL SUNBLOCK SPF 30- octocrylene, octyl methoxycinnamate, octyl salicylate, oxybenzone lotion**

**Derma Soleil**

*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.*

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**Derma Soleil Natural Age-Free Facial Sunblock SPF 30**

**Drug Facts**

**Active Ingredient**

- Octocrylene 4%
- Octyl Methoxycinnamate 7.5%,
- Octyl Salicylate 4%,
- Oxybenzone 5%

**Purpose**

Sunscreen

**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. 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.

**Directions**

• 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

**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.

## PRINCIPAL DISPLAY PANEL - 120 ml Tube

### Derma Soleil

Natural Age-Free Facial Sunblock

Moisturizing with Vitamins A, C, E & Aloe

UVA+UVB Protection

Water Resistant (40 minutes)

PABA Free

For All Skin Types

Broad Spectrum

SPF 30+

Net 4 fl. Oz (120 ml)



## DERMA SOLEIL NATURAL AGE-FREE FACIAL SUNBLOCK SPF 30

octocrylene, octyl methoxycinnamate, octyl salicylate, oxybenzone lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69711-310
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	4 g in 100 mL
<b>OXYBENZONE</b> (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	5 g in 100 mL
<b>OCTOCRYLENE</b> (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	4 g in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>GLYCERIN</b> (UNII: PDC6 A3C0 OX)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420 LU)	
<b>EVENING PRIMROSE OIL</b> (UNII: 3Q9L08K71N)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>GRAPE SEED OIL</b> (UNII: 930MLC8XGG)	
<b>CHAMOMILE FLOWER OIL</b> (UNII: 60F80Z61A9)	
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
<b>HYDROLYZED WHEAT PROTEIN (ENZYMATIC, 3000 MW)</b> (UNII: J2S07SB0YL)	
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>GLYCERYL CAPRYLATE</b> (UNII: TM2TZD4G4A)	
<b>CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 71DD5V995L)	
<b>AVOCADO OIL</b> (UNII: 6VNO72PFC1)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SODIUM LEVULINATE</b> (UNII: VK44E1MQU8)	
<b>SODIUM ANISATE</b> (UNII: F9WFJ28MV9)	
<b>CARBOMER INTERPOLYMER TYPE A (55000 CPS)</b> (UNII: 59TL3WG5CO)	
<b>AMINOMETHYLPROPANOL</b> (UNII: LU49E6626Q)	
<b>CARBOXYPOLYMETHYLENE</b> (UNII: 0A5MM307FC)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69711-310-04	120 mL in 1 TUBE; Type 0: Not a Combination Product	07/20/2017	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/20/2017	

**Labeler** - Derma Soleil (079767886)

Revised: 7/2017

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