

# **DERMA SOLEIL NATURAL 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 Sunblock SPF 30**

### **Drug Facts**

#### **Active Ingredients**

- 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 Health**

**Natural Sunblock SPF 30**

80% Natural

Moisturizing with Vitamins A, C, E & Aloe

UVA+UVB Protection

Water Resistant (40 minutes)

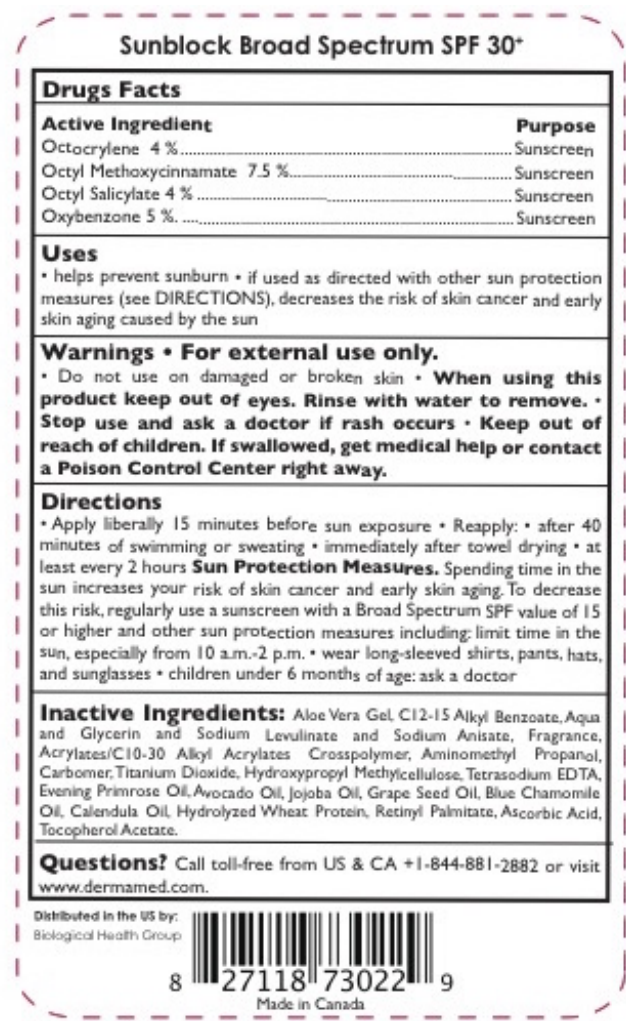
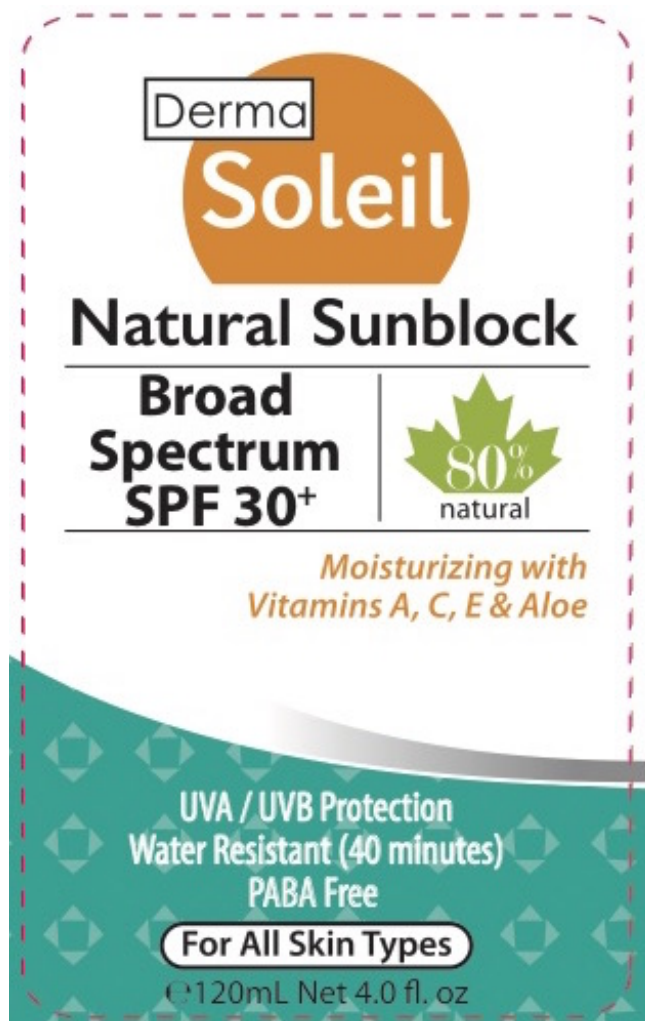
PABA Free

For All Skin Types

Broad Spectrum

SPF 30+

Net 4 fl. Oz (120 ml)



**PRINCIPAL DISPLAY PANEL - 240 ml Tube**

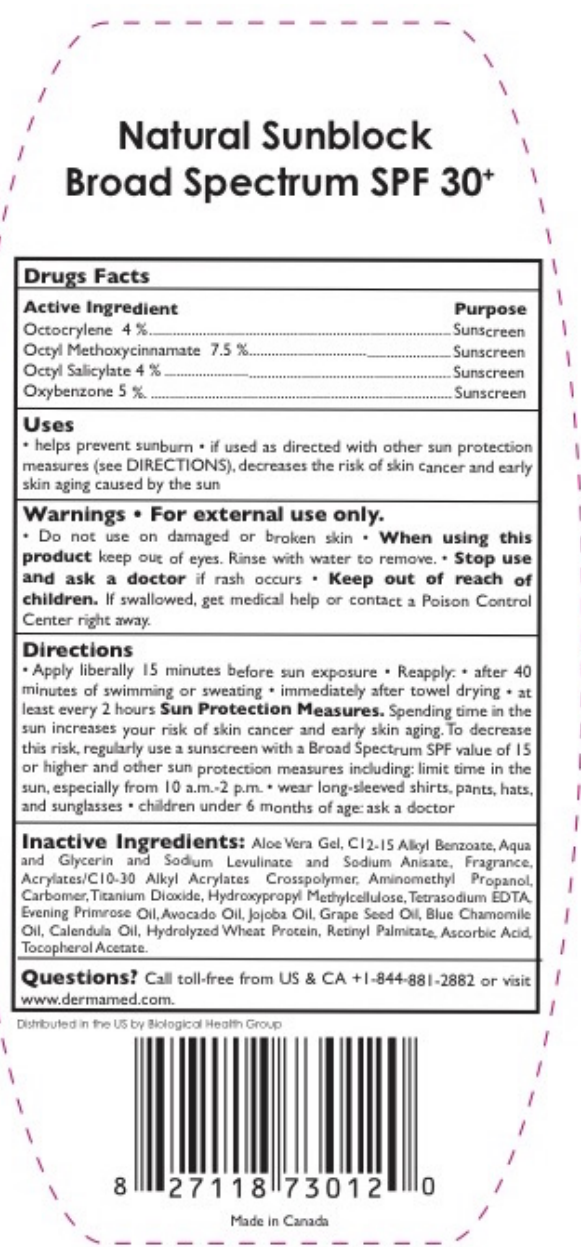
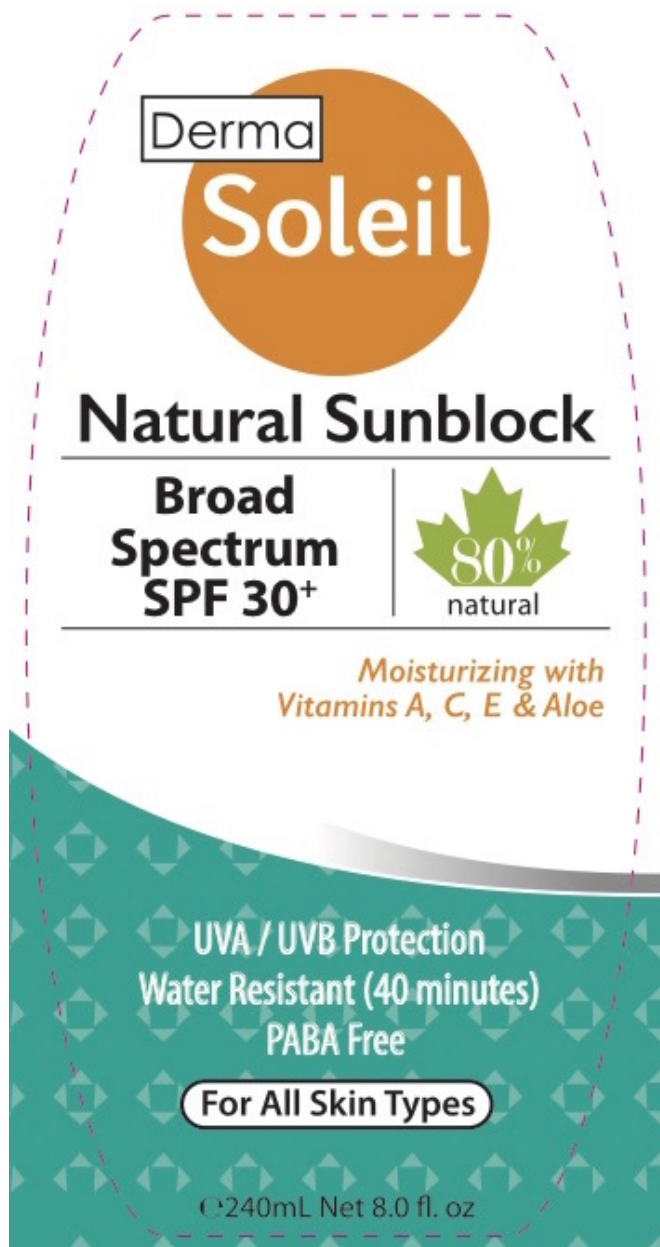
**Derma Soleil Health**

**Natural Sunblock SPF 30**

80% Natural

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 8 fl. Oz (240 ml)



<b>DERMA SOLEIL NATURAL SUNBLOCK SPF 30</b>			
octocrylene, octyl methoxycinnamate, octyl salicylate, oxybenzone lotion			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69711-305
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	4 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE SODIUM (UNII: MP1J8420LU)	
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)	
JOJOBA OIL (UNII: 724GKU717M)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
WATER (UNII: 059QF0KO0R)	
SODIUM LEVULINATE (UNII: VK44E1MQU8)	
SODIUM ANISATE (UNII: F9WFJ28MV9)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
HYDROLYZED WHEAT PROTEIN (ENZYMATIC, 3000 MW) (UNII: J2S07SB0YL)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69711-305-01	120 mL in 1 TUBE; Type 0: Not a Combination Product	07/20/2017	
2	NDC:69711-305-02	240 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	

