

DERMA SOLEIL KIDS NATURAL SUNBLOCK SPF 45- 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.

Derma Soleil Kids Natural Sunblock SPF 45

Drug Facts

Active Ingredients

- Octocrylene 7%
- Octyl Methoxycinnamate 7.5%,
- Octyl Salicylate 5%,
- Oxybenzone 6%

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

Kids Natural Sunblock SPF 45

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 45+

Net 4 fl. Oz (120 ml)



Kids 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

• 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 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

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.dermamed.com.

Distributed in the US by:
Biological Health Group



Made in Canada

PRINCIPAL DISPLAY PANEL - 240 ml Tube

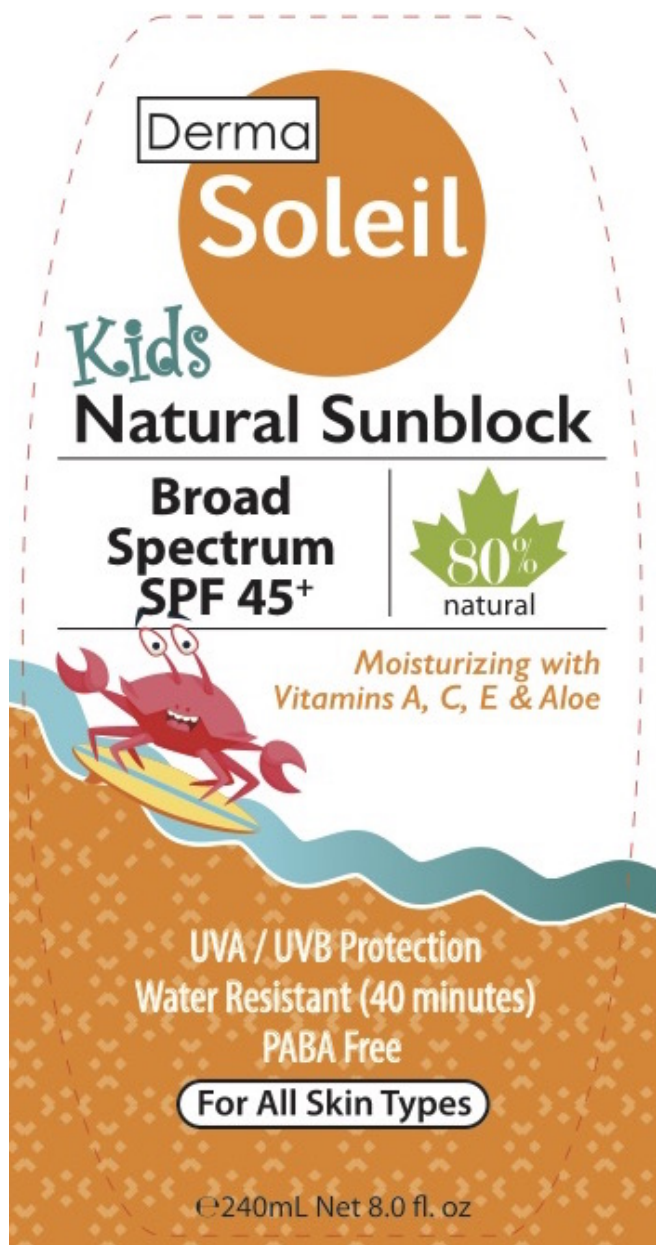
Derma Soleil

Kids Natural Sunblock SPF 45

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 45+
 Net 8 fl. Oz (240 ml)



Kids Natural 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

• 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 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

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.dermamed.com.

Distributed in the US by Biological Health Group



Made in Canada

DERMA SOLEIL KIDS NATURAL SUNBLOCK SPF 45

octocrylene, octyl methoxycinnamate, octyl salicylate, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69711-457
Route of Administration	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	5 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 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:69711-457-01	120 mL in 1 TUBE; Type 0: Not a Combination Product	07/20/2017	
2	NDC:69711-457-02	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	

