

SOLAR DEFENDER SPF 30- octinoxate, zinc oxide lotion
Shine & Pretty (USA), Corp.

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.

Solar Defender SPF 30

Active Ingredients

Octinoxate, 7.5% (UVB sunscreen), Zinc oxide, 10.0% (UVA/UVB sunscreen)

Warnings

For external use only, not to be swallowed. Avoid contact with eye. Discontinue if signs of irritation or rash appear.

Purpose

For Sun protection for surfaces of skin, face, arm and hand. SPF-15 provides the face and body skin with effective protection against harmful UVA and UVB rays. Use daily over moisture cream to help prevent premature aging and wrinkling due to prolonged exposure to the sun, reapply after swimming or excessive exercise.

Paraben and PABA free.

Fairly water resistant.

Not tested on animals.

Made in the USA specifically for professional dermatology and esthetic practices.

Directions for Use

Home Care: Apply Solar Defender SPF 30 liberally to face and body at least ten minutes before sun exposure or two minutes before applying makeup. Reapply after swimming or excessive perspiration. As part of effective age-fighting program, apply every morning throughout the year. Because Solar Defender SPF 30 is a blend of UV absorbing and reflecting sunscreens, it may be applied over or under moisturizer.

Facial Procedure: Solar Defender SPF 30 is recommended as the finishing product at the end of the facial procedure for any skin type. It may be applied over finishing cream or moisturizer. It should not be rubbed in completely, but left on the skin until it becomes transparent.

Inactive Ingredients

Water, ethylhexyl palmitate, cyclomethicone, laurylmethicone, butylene glycol, tocopheryl acetate, sodium chloride, kukui (aleurites moluccana) seed oil (lipid-rich plant oil), green tea (camellia oleifera) seed extract, aloe vera (aloe barbadensis) leaf extract, tetrahexyldecyl ascorbate (time-released age-fighting vitamin C), allantoin, sodium PCA (hydrating), disodium EDTA, ethylhexylglycerin, methylisothiazolinone, fragrance (synthetic citrus).

Questions?

(805) 388-8581

Keep out of the reach of children

Keep Out of the reach of children. Use on children under six months of age only with the advice of a physician.

Principal Panel Display

MM1



Drug Facts	
Active Ingredients	Purpose
Octinoxate 7.5%	Sunscreen UVB
Zinc Oxide 10.0%	Sunscreen UVA/UVB
Uses	
<ul style="list-style-type: none"> • Broad-spectrum UV protection with micronized Zinc Oxide goes on sheer, is in visible in seconds • Easy to wear everyday, under makeup or alone • Gentle, greaseless formula is enriched with the age-fighting antioxidant Vitamins C and E, plus soothing Green Tea and Aloe 	
Warnings	
For external use only	
Keep out of eyes. Rinse with water to remove.	
Discontinue use if signs of irritation or rash appear	
For children under 6 months of age, consult a doctor	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately	
Directions	
<ul style="list-style-type: none"> • Apply liberally to face or body at least ten minutes before sun exposure or two minutes before applying makeup. • Reapply after swimming or excessive perspiration. • As part of an effective age-fighting program, apply every morning throughout the year. • May be applied over or under moisturizer. 	
Inactive Ingredients	
Water, ethylhexyl palmitate, cyclomethicone, lauryl-methicone, butylene glycol, tocopheryl acetate, sodium chloride, kukui (<i>aleurites moluccana</i>) seed oil, green tea (<i>camellia oleifera</i>) seed extract, aloe vera (<i>aloe barbadensis</i>) leaf extract, tetrahexyldecyl ascorbate, allantoin, sodium PCA, disodium EDTA, ethylhexylglycerin, methylisothiazolinone, fragrance.	

SOLAR DEFENDER SPF 30
UVA/UVB HIGH PROTECTION SUNSCREEN

SOLAR DEFENDER SPF 30

octinoxate, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59663-110
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
CHAMOMILE (UNII: FGL3685T2X)	
CUCUMBER (UNII: YY7C30VXJT)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
KUKUI NUT (UNII: J87WJ3E7VW)	
CAMELLIA OLEIFERA SEED (UNII: 59ED29FM2J)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
ALLANTOIN (UNII: 344S277G0Z)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59663-110-04	120 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/01/2013	

Labeler - Shine & Pretty (USA), Corp. (603528605)

Revised: 2/2013

Shine & Pretty (USA), Corp.