

SELECT BRAND SUNSCREEN - octinoxate, oxybenzone lotion

Select Brand Distributors

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.

Drug Facts

Active ingredients

Octinoxate 7.5%

Oxybenzone 4.5%

Purpose

Sunscreen

Uses

- Sun Protection Factor 15
- helps prevent sunburn
- retains SPF after 80 minutes of activity in water

Warnings

For external use only

When using this product

- keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

- rash or irritation develops and lasts.

Keep out of the reach of children.

If swallowed get medical help or contact a Poison Control Center right away.

Directions

- shake well
- apply generously and evenly before sun exposure and as needed
- children under 6 months of age: ask a doctor
- reapply frequently and after towel drying, swimming or perspiring

Inactive ingredients

Water, Stearic Acid, Sorbitan Oleate, Sorbitol, Glyceryl Stearate SE, Hydrogenated Soybean Oil, Isopropyl Myristate, Triethanolamine, VP/Eicosene Copolymer, Benzyl Alcohol, Dimethicone, Carbomer, Simmondsia Chinensis (Jojoba) Seed Oil, Tocopherol, Disodium EDTA, Aloe Barbadensis Leaf Juice, Imidazolidinyl Urea, Methylparaben, Propylparaben, Fragrance.

Principal Display Panel

select brand

the lower price name brand

SUNSCREEN

LOTION

15 SPF

Very Water Resistant

UVA/UVB Protection

Vitamin E and Aloe

8 FL OZ (237 mL)

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the lower price name brand

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LOTION

15 SPF

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Resistant
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Protection



Vitamin E & Aloe

8 FL OZ (237 ml)

S804-A



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:15127-000
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 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	4.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
HYDROGENATED SOYBEAN OIL (UNII: A2M91M918C)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
TROLAMINE (UNII: 9O3K93S3TK)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
IMIDUREA (UNII: M629807ATL)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
JOJOBA OIL (UNII: 724GKU717M)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
TOCOPHEROL (UNII: R0ZB2556P8)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15127-000-16	226 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/16/2012	

Labeler - Select Brand Distributors (043562370)

Revised: 11/2012

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