OP PROTECTIVE XTREME TANNING 8 - octinoxate, octisalate lotion
Sun & Skin Care Research, LLC

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 4.5%
Octisalate 5.0%

Purpose

Sunscreen

Uses
- Helps prevent sunburn

Warnings

Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, **not** skin cancer or early skin aging.

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 the reach of children.** If swallowed, get medical help or call a poison control center right away.

Directions
- apply evenly and liberally to all exposed areas 15 minutes before sun exposure. Ensure skin is completely covered with product.
- reapply after 40 minutes of swimming or sweating, immediately after towel drying and at least every 2 hours
- children under 6 months: Ask a doctor

Other Information
- protect this product from excessive heat and direct sun
- for use on skin only
- avoid contact with fabric

Ocean Potion® clean synthesized dry tanning lotion glides on easily for quick absorption, while enlisting Aloe Vera and anti-oxidant vitamins A and E that aid in the reduction of cell damaging free radicals for maintaining younger looking skin.

Drug Facts

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- reapply:
  - after 40 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours
- children under 6 months: Ask a doctor

Inactive Ingredients: Water, Glycerin, Brassica Napus (Canola) Oil, Helianthus Annuus (Sunflower) Seed Oil, Propylene Glycol, Fragrance, Caramel, Aloe Barbadensis Leaf Extract, Retinyl Palmitate (Vitamin A), Tocopheryl Acetate (Vitamin E), Macrocystis Pyrifera (Kelp) Extract, Sorbitan Oleate, Olea Europaea (Olive) Fruit Oil, Carbomer, Hydroxypropyl Methylcellulose, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Disodium EDTA, Triethanolamine, Phenoxyethanol (&) Methyl (&) Butyl (&) Ethyl (&) Propyl (&) Isobutyl Parabens.

Other Information
- protect this product from excessive heat and direct sun

cruelty free

0 00774 00690 1

Manufactured and Distributed by

Sun & Skin Care Research, Inc.

851 Greensboro Rd., Cocoa, FL 32926

Made in U.S.A. ***www.oceanpotion.com***

1-800-715-3485

Black Silk screen white
PMS Yellow PMS1375 PMS300
PMS 498 die line

OP PROTECTIVE XTREME TANNING 8

octinoxate, octisalate lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62802-690
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4.5 mL in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
CARAMEL (UNII: T9D99G2B1R)	
CANOLA OIL (UNII: 331KBJ17RK)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN3152OP35)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYISOBUTYLENE (2300 MW) (UNII: DSQ2V1DD1K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:62802-690-08	237 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2012	

Labeler - Sun & Skin Care Research, LLC (849772207)

Establishment

Name	Address	ID/FEI	Business Operations
Sun & Skin Care Research, LLC		849772207	manufacture

Revised: 5/2012 Sun & Skin Care Research, LLC