

OP DARK TANNING GEL 4 - octinoxate, octisalate spray
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 3.0%

Octisalate 2.0%

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

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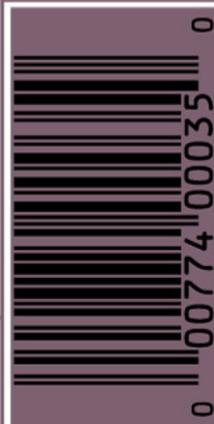
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 - at least every 2 hours
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Inactive Ingredients Acrylates / C10-30 Alkyl Acrylate Crosspolymer, Acrylates Copolymer, Aloe Barbadensis Leaf Extract, Arctium Majus Root Extract, Butylparaben, Calendula Officinalis Flower Extract, Caramel Color P212, Chamomilla Recutita (Matricaria) Flower Extract, Disodium, EDTA, Ethylparaben, Fragrance, Honey Extract, Hydrastis Canadensis (Golden Seal) Extract, Isobutylparaben, Macrocystis Pyrifera Extract, Methylparaben, Olea Europaea Fruit Oil, Phenoxyethanol, Polyisobutene, Propylene Glycol, Propylparaben, Retinyl Palmitate, Sorbitan Oleate, Symphytum Officinale Leaf Extract, Tilia Cordata Flower Extract, Tocopheryl Acetate, Triethanolamine, Water

Other Information

- protect this product from excessive heat and direct sun



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



Dark Tanning
SPRAY
Gel
OIL FREE

Water Resistant
(40 minutes)

8.5 FL OZ
(251mL)

SPF 4
4

Black Silk screen white
PMS300 PMS Yellow PMS1375
PMS 5275 (opaque silk screen)
die line

octinoxate, octisalate spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62802-035
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.0 mL in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	2.0 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLPARABEN (UNII: 3QP1IU3FV8)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLPARABEN (UNII: 14255EXE39)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYISOBUTYLENE (2300 MW) (UNII: DSQ2V1DD1K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
CARAMEL (UNII: T9D99G2B1R)	
OLIVE OIL (UNII: 6UYK2W1W1E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62802-035-85	251 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