

OP DARK FORMULA XTREME TANNING 4 - 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 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

This lightweight moisturizing formula glides on easily for quick absorption while providing minimal sun protection. Aloe Vera and anti-oxidant vitamins A and E aid in the reduction of cell damaging free radicals and help to maintain younger looking skin. For skin that tans easily.

Drug Facts

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|----------------------------------|-----------|
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Inactive Ingredients: Acrylates / C10-30 Alkyl Acrylate Copolymer, Acrylates Copolymer, Aloe Barbadensis Leaf Extract, Brassica Napus (Canola) Oil, Butylparaben, Caramel Color P212, Carbomer, Disodium EDTA, Ethylparaben, Fragrance, Glycerin, Helianthus Annus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Isobutylparaben, Macrocystis Pyrifera Extract, Methylparaben, Olea Europaea Fruit Oil, Phenoxyethanol, Polyisobutene, Propylene Glycol, Propylparaben, Retinyl Palmitate, Sorbitan Oleate, 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 Formula
XTREME
4
TANNING LOTION

with Aloe Vera
& Vitamin E

SPF 4

8 FL OZ (237 mL)

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

OP DARK FORMULA XTREME TANNING 4

octinoxate, octisalate lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62802-600 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 3 mL in 100 mL |
| OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W) | OCTISALATE | 2 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALOE VERA LEAF (UNII: ZY8 1Z83H0 X) | |
| CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809 Y72KV36) | |
| 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: 3QPII03FV8) | |
| 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 MONOLEATE (UNII: 06XEA2VD56) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| WATER (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:62802-600-08 | 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