

OP PROTECTIVE GEL 15- 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 7.5%
- 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



Drug Facts

Active Ingredients } Purpose
 Octinoxate 7.5%, Octisalate 5.0% } 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 reach of children. If swallowed, get medical help or contact 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
- at least every 2 hours
- children under 6 months: Ask a doctor

Inactive Ingredients: Acrylates Copolymer, Acrylates / C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Extract, Arctium Majus Root Extract, Butylparaben, Calendula Officinalis Flower Extract, Caramel, 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, Polyisobutane, 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
- for use on skin only



00039-01001

No Animal Testing

Manufactured and Distributed by
Sun & Skin Care Research, LLC
 851 Greensboro Rd., Cocoa, FL 32926
 oceanpotion.com 800-715-3485



OP PROTECTIVE GEL 15

octinoxate, octisalate spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62802-039
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
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5.0 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLPARABEN (UNII: 3QPIU3FV8)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLPARABEN (UNII: 14255EXE39)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYISOBUTYLENE (2300 MW) (UNII: DSQ2V1DD1K)	
HONEY (UNII: Y9H1V576FH)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CHAMOMILE (UNII: FGL3685T2X)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
HYDRASTIS CANADENSIS WHOLE (UNII: R763EBH88T)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
SYMPHYTUM OFFICINALE WHOLE (UNII: H8FJJ6KX5Y)	
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:62802-039-85	251 g 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
------	---------	--------	---------------------

Revised: 7/2014

Sun & Skin Care Research, LLC