

**OP PROTECTIVE SPRAY GEL 8 - octinoxate, octisalate spray**  
**Sun & Skin Care Research, Inc**

*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.*

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**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

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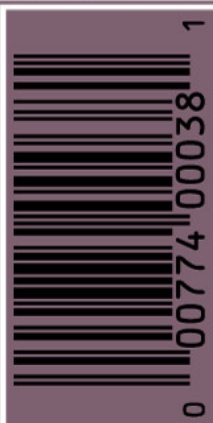
### Directions

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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** 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](http://www.oceanpotion.com)

1-800-715-3485



**PROTECTIVE  
SPRAY  
Gel  
OIL FREE**

**Water  
Resistant**  
(40 minutes)

8.5 FL OZ  
(251mL)

**SPF 8  
8**

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

octinoxate, octisalate spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62802-038
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4.5 mL in 100 mL
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5.0 mL in 100 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 1G56KV7BUJ)	
<b>ALOE VERA LEAF</b> (UNII: ZY8 1Z83H0 X)	
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>BUTYLPARABEN</b> (UNII: 3QP1IU3FV8)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>ETHYLPARABEN</b> (UNII: 14255EXE39)	
<b>ISOBUTYLPARABEN</b> (UNII: 0QQJ25X58G)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POLYISOBUTYLENE (2300 MW)</b> (UNII: DSQ2V1DD1K)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>SORBITAN MONOLEATE</b> (UNII: 06XEA2VD56)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CARAMEL</b> (UNII: T9D99G2B1R)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:62802-038-85	251 mL in 1 BOTTLE		

### Marketing Information

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

**Labeler** - Sun & Skin Care Research, Inc (849772207)

## Establishment

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

Revised: 3/2012

Sun & Skin Care Research, Inc