# OP PROTECTIVE MIST 15 OIL FREE - 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.

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#### **DRUG FACTS**

## **Active Ingredients**

Octinoxate 7.0% 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 away from face to avoid breathing in. 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. **Flammable** Do not use near heat, flame or while smoking. Avoid long term storage above 104° F (40° C). Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperatures above 120° F.

#### **Directions**

- spray evenly and liberally to all exposed areas 15 minutes before sun exposure. Ensure skin is completely covered with product.
- hold can 4 6 inches away from the skin to apply
- do not spray directly on face. Spray on hands then apply to face.
- do not apply in windy conditions. Use in a well ventilated area.
- 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



Ocean Potion® SPF 15 Protective Spray Gel offers moderate sunburn protection for all your outdoor activities. This oil-free instant drying formula is perfect for slow tanning.

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   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.

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**Inactive Ingredients** Acrylates/Octylacrylamide Copolymer, Glycerin, Fragrance, SD Alcohol 40

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#### **Questions or comments?**

Call toll free 1-800-715-3485

Manufactured and distributed by SUN AND SKIN CARE RESEARCH, INC.

851 Greensboro Rd., Cocoa, FL 32926 www.oceanpotion.com Made in U.S.A. DO



## OP PROTECTIVE MIST 15 OIL FREE

6 FL OZ (177mL)

octinoxate, octisalate spray

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source)

NDC:62802-915

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.0 mL in 100 mL
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5.0 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6 A3C0 OX)	

I	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62802-915-06	177 mL in 1 CAN		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	0 1/0 1/20 12		

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

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

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