# OCEAN POTION INSTANT DRY 70 MIST SUNSCREEN - avobenzone, homosalate, octisalate, octocrylene, oxybenzone 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**

- Homosalate: 15%
- Oxybenzone: 6%
- Octisalate: 5%
- Octocrylene: 3%
- Avobenzone: 2%

## Purpose

Sunscreen

## Uses

- helps prevent sunburn
- If used as directed with other skin protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

## Warnings

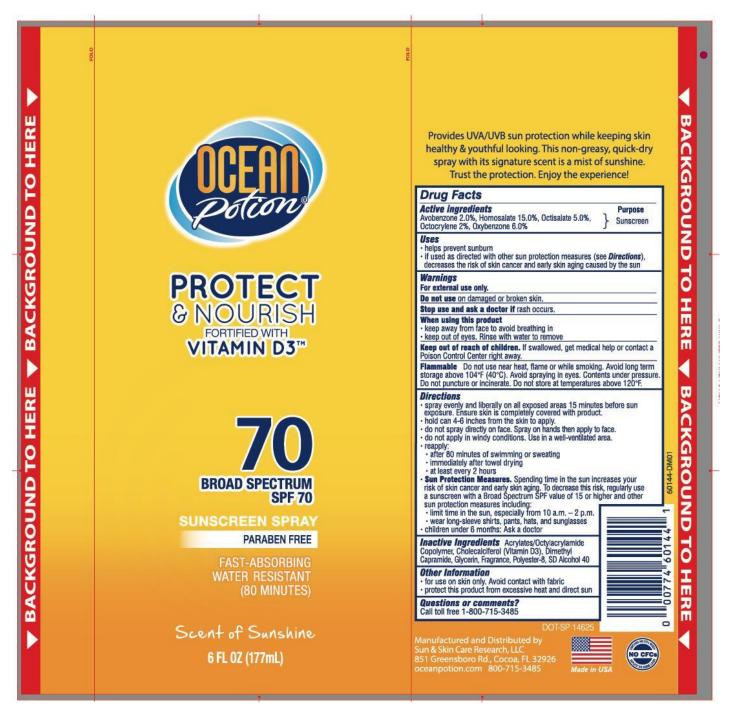
**For external use only. Do not use** on damaged or broken skin. **Stop use and ask a doctor if** rash occurs. **When using this product** keep away from face to avoid breathing in. Rinse with water to remove. **Keep out of the reach of children.** If swallowed, get medical help or contact a Poison Control 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 in temperatures above 120°F.

## Directions

- spray evenly and liberally on 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 80 minutes of swimming or sweating and immediately after towel drying
- at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including limiting time in the sun, especially from 10a.m.-2p.m., wear long-sleeved shirts, pants hats and sunglasses.
- children under 6 months: Ask a doctor

## **Other Information**

- For use on skin only
- Avoid contact with fabric
- Protect this product from excessive heat and direct sun



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Product Information			
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:62802-644
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety								
Ingredient Name				of Strength	Strength			
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)			HOMOS	SALATE	15 g in 100 g			
OCTISALATE (UNII: 4X49	OCTISA	ALATE	5 g in 100 g					
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)				CRYLENE	2 g in 100 g			
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)			AVOBE	AVOBENZONE				
OXYBENZONE (UNII: 950	OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)			OXYBENZONE				
Inactive Ingredients								
Ingredient Name								
ALCOHOL (UNII: 3K9958V90M)								
CHOLECALCIFEROL (UNII: 1C6V77QF41)								
DIMETHYL CAPRAMIDE (UNII: O29 Y6 X2 JEZ)								
GLYCERIN (UNII: PDC6A3C0OX)								
POLYESTER-8 (1400 MW, CYANO DIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)								
Packaging								
# Item Code	Package Description	Marketing Start Date		Marketing End Date				
1 NDC:62802-644-06	177 g in 1 CAN			U				
Marketing Information								
Marketing Category	Application Number or Monog	raph Citation	Marketing Start	Date Marke	ting 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(62802-644)

Revised: 7/2014

Sun & Skin Care Research, LLC