

# OCEAN POTION INSTANT DRY 50 MIST SUNSCREEN - avobenzone, homosalate, octisalate, octocrylene 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%

Octisalate: 5%

Octocrylene: 7%

Avobenzone: 3%

### 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 spray 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

<b>Top of Can</b>																																
<b>Shoulder</b> 41 mm		<p><i>This non-greasy, instant drying formula is ideal for all outdoor activities. Each 1 oz application delivers 200 IU of Vitamin D3 to your skin.</i></p>	<table border="1"> <tr> <th colspan="2">Drug Facts</th> </tr> <tr> <td><b>Active ingredients</b></td> <td><b>Purpose</b></td> </tr> <tr> <td>Avobenzone 3.0%, Homosalate 15.0%, Octisalate 5.0%, Octocrylene 7.0%</td> <td>Sunscreen</td> </tr> <tr> <td colspan="2"><b>Uses</b></td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> <li>• helps prevent sunburn</li> <li>• if used as directed with other sun protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun</li> </ul> </td> </tr> <tr> <td colspan="2"><b>Warnings</b></td> </tr> <tr> <td colspan="2"> <p><b>For external use only.</b></p> <p><b>Do not use</b> on damaged or broken skin.</p> <p><b>Stop use and ask a doctor</b> if rash occurs.</p> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>• keep away from face to avoid breathing in</li> <li>• keep out of eyes. 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### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62802-647
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Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 mL in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mL in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 mL in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62802-647-06	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	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