OCEAN POTION INSTANT DRY 30 MIST WATER SPORT 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.

Drug Facts

Active Ingredients

Homosalate: 13% Octisalate: 5% Octocrylene: 6% 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.

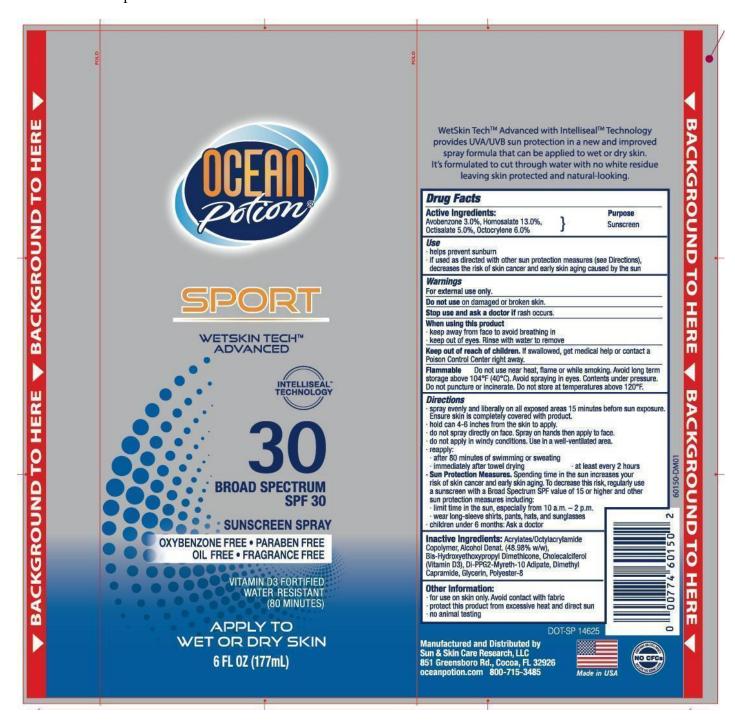
Directions

- 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 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



OCEAN POTION INSTANT DRY 30 MIST WATER SPORT SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene spray

HUMAN OTC DRUG	Item Code (Source)	NDC:62802-651	
TO DIC A I			
TOPICAL			
Active Ingredient/Active Moiety			
t	v	y	

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	13 g in 100 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	6 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g

Inactive Ingredients				
Ingredient Name	Strength			
ALCOHOL (UNII: 3K9958V90M)				
CHOLECALCIFEROL (UNII: 1C6 V77QF41)				
DIMETHYL CAPRAMIDE (UNII: O29 Y6 X2JEZ)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYESTER-8 (1400 MW, CYANO DIPHENYLPRO PENO YL CAPPED) (UNII: T9296 U138P)				
BIS-HYDRO XYETHO XYPRO PYL DIMETHICO NE (37 CST) (UNII: 7K226 YI89 Y)				
DI-PPG-2 MYRETH-10 ADIPATE (UNII: 4IN30 1M0 KJ)				

Packaging	\$			
# Ite	m Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:6280	2-651-06	77 g 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 14		

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Sun & Skin Care Research, LLC		849772207	manufacture(62802-651)	

Revised: 3/2014 Sun & Skin Care Research, LLC