OCEAN POTION COOL DRY TOUCH SPORT 30 SUNSCREEN - avobenzone, homosalate, octisalate, octocrylene lotion 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.

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 out of eyes. 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.

Directions

- apply liberally 15 minutes before sun exposure
- 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

VITAMIN D IS ESSENTIAL TO YOUR HEALTH. EACH 1 OZ APPLICATION DELIVERS 200 IU OF VITAMIN D3 TO YOUR SKIN. FORMULATED WITHOUT HARSH INGREDIENTS SUCH AS OXYBENZONE AND PARABENS.

THIS FRAGRANCE FREE. OIL FREE SUNSCREEN OFFERS BROAD SPECTRUM PROTECTION AGAINST HARMFUL UVA/UVB EXPOSURE.

Drug Facts

Active Ingredients Purpose Avobenzone 3.0%, Homosalate 15.0%. Octisalate 5.0%, Octocrylene 7.0% Sunscreen Uses helps prevent sunburn ■ if used as directed with other sun

protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

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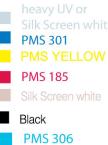
Inactive Ingredients Acrylates / C10-30 Alkyl Acrylate Crosspolymer, Acrylates Copolymer, Caprylyl Glycol, Carborner, Cholecalciferol, Diisopropyl Adipate, Dimethyl Capramide, Disodium EDTA, Hydroxypropyl Methylcellulose, Macrocystis Pyrifera Extract, Menthol, Phenoxyethanol, Polyester-8, Propylene Glycol, Silica, Sorbitan Oleate, Tocopheryl Acetate, Triethanolamine, Water

Other Information

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1-800-715-3485





Water Resistant (80 minutes) 8 fl oz (237mL)

Vitamin D₃ Fortified

OCEAN POTION COOL DRY TOUCH SPORT 30 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62802-148			
Route of Administration	TOPICAL					

	Ingredient Name		Basis of Strengt	th Strength
OMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)			HOMOSALATE	15 mL in 100 mL
OCTISALATE (UNII: 4X49 Y0 596 W) (OCTISALATE - UNII:4X49 Y0 596 W)			OCTISALATE	5 mL in 100 mL
OCTOCRYLENE (UNII: 5A	DCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)		OCTOCRYLENE	7 mL in 100 mL
AVOBENZONE (UNII: G63	BQQF2NOX) (AVOBENZONE - UNII:G	63QQF2NOX)	AVOBENZONE	3 mL in 100 mL
Inactive Ingredients				
	Ingredient I	Name		Strengtl
WATER (UNII: 059QF0KO	0 R)			
CARBOMER COPOLYME	ER TYPE B (ALLYL PENTAERYTHR	ITOL CROSSLINKED) (UNII: 1G56KV7BUJ)	
CAPRYLYL GLYCOL (UN	NII: 00YIU5438U)			
CARBOMER HOMOPOLY	YMER TYPE C (UNII: 4Q93RCW27E)			
CHOLECALCIFEROL (UN	NII: 1C6V77QF41)			
DIISOPROPYL ADIPATE	(UNII: P7E6 YFV72X)			
DIMETHYL CAPRAMIDE	(UNII: O29Y6X2JEZ)			
EDETATE DISODIUM (UN	NII: 7FLD91C86K)			
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)			
PHENOXYETHANOL (UN	II: HIE492ZZ3T)			
POLYESTER-8 (1400 MW	V, CYANO DIPHENYL PROPENO YL (C APPED) (UNII: T9296U	J138P)	
PROPYLENE GLYCOL (U	JNII: 6DC9Q167V3)			
SORBITAN MONOOLEA	TE (UNII: 06XEA2VD56)			
ALPHA-TOCOPHEROL A	CETATE (UNII: 9E8X80D2L0)			
TROLAMINE (UNII: 903K	93S3TK)			
MENTHOL (UNII: L7T10EI	P3A)			
Packaging				
# Item Code	Package Description	Marketing Star	t Date Mar	keting End Date
1 NDC:62802-148-08	237 mL in 1 BOTTLE			
Marketing Inform	mation			
Marketing Category	Application Number or Monog	raph Citation Mar	keting Start Date	Marketing End Date
OTC monograph not final	part352	- 0 1/0 1/	/20.12	

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

Establishment

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