## PARROT HEAD FINS UP SPORT 15 - avobenzone, homosalate,octisalate lotion 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: 7.5% Octisalate: 5% Avobenzone: 1.2%

## 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 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

**Fins Up! Sport** with **WetSkin Tech™** is a high performance sunscreen. It dries fast, bonds to your skin without running into your eyes and stinging. It provides maximum water resistance whether

sweating, swimming or in high humidity. The Aloe Hydrating Complex™ 200 fortified with vitamins

A & E keeps your skin hydrated and rejuvenated. **Drug Facts** Active Ingredients Purpose Homosalate 7.5%, Octisalate 5.0%, Avobenzone 1.2% 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 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 reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Directions apply liberally 15 minutes before sun exposure apply liberally 15 minutes before sun exposure
reapply:

 after 80 minutes of swimming or sweating
 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: • limit time in the sun, especially from 10 a.m. - 2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses children under 6 months: Ask a doctor Inactive Ingredients Arcylates (701-30 Alkyl Acrylate Crosspolymer, Acrylates Copolymer, Aloe Barbadensis Leaf Extract, Caprylyl Glycol, Carborner, Diisopropyl Adipate, Dimethyl Capramide, Disodium EDTA, Hydroxypropyl Methylcellulose, Isohexadecane, Olea Europaea (Olive) Fruit Oli, Phenoxyettanol, Polyester-8, Propaeatiol, Retinyl Palmitate, Saccharide Isomerate, Sorbitan Oleate, Tocopheryl Acetate, Triethanolamine, Water Other Information ■ For use on skin only. Avoid contact with fabric protect this product from excessive heat and direct sun Manufactured and Distributed by Sun & Skin Care Research, Inc. 851 Greensboro Road, Cocoa, Florida 32926 1-800-715-3485 Made in USA Margaritaville® and Parrot Head

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#### **PARROT HEAD FINS UP SPORT 15** avobenzone, homosalate, octisalate lotion **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:62802-109 **Route of Administration** TOPICAL **Active Ingredient/Active Moiety Basis of Strength Ingredient Name** Strength HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S) HOMOSALATE 7.5 mL in 100 mL 5 mL in 100 mL OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W) OCTISALATE AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) **AVOBENZONE** 1.2 mL in 100 mL

FREE

<b>Inactive Ingredients</b>	3							
Ingredient Name								
WATER (UNII: 059QF0KO0R)								
CAPRYLYL GLYCOL (U	NII: 00YIU5438U)							
CARBOMER INTERPOL	YMER TYPE A (55000 MPA.S) (UNI	I: 59TL3WG5CO)						
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)								
DIISOPROPYL ADIPATE (UNII: P7E6 YFV72X)								
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)								
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)								
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)								
PHENO XYETHANOL (UNII: HIE492ZZ3T)								
POLYESTER-8 (1400 MW, CYANO DIPHENYLPROPENO YL CAPPED) (UNII: T9296U138P)								
PROPANEDIOL (UNII: 59	65N8W85T)							
SORBITAN MONOOLEA	TE (UNII: 06XEA2VD56)							
ALPHA-TOCOPHEROL A	ACETATE (UNII: 9E8X80D2L0)							
TROLAMINE (UNII: 903K93S3TK)								
ISO HEXADECANE (UNII: 918 X10 UF1E)								
OLIVE OIL (UNII: 6UYK2	W1W1E)							
SACCHARIDE ISO MERA	<b>ΓΕ</b> (UNII: W8K377W98I)							
VITAMIN A PALMITATE	(UNII: 1D1K0 N0 VVC)							
Packaging								
# Item Code	Package Description	Marketing	g Start Date	Ma	arketing l	End Date		
<b>1</b> NDC:62802-109-06	177 mL in 1 BOTTLE							
Marketing Infor								
Marketing Category	Application Number or Mono	graph Citation	Marketing Star	t Date	Marketi	ng End Dat		
OTC monograph not final	part352		05/10/2012					

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