PARROT HEAD DEDICATED TO SUNSHINE TAN ENHANCER 15 - octinoxate, octis alate s pray 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

Octinoxate 7.5% Octisalate 5.0%

Purpose

Sunscreen

Uses

• Helps prevent sunburn

Warnings

Skin Cancer / **Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, **not** skin cancer or early skin aging.

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 call a poison control center right away.

Directions

- apply evenly and liberally to all exposed areas 15 minutes before sun exposure. Ensure skin is completely covered with product.
- reapply after 40 minutes of swimming or sweating, immediately after towel drying and at least every 2 hours
- children under 6 months: Ask a doctor

Other Information

- protect this product from excessive heat and direct sun
- for use on skin only

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INACTIVE INGREDIENTS ACRYLATES / C10-30 ALKYL ACRYLATE CROSSPOLYMER, ACRYLATES COPOLYMER, ALOE BARBADENSIS LEAF EXTRACT, ARCTIUM MAJUS ROOT EXTRACT, BUTYL-PARABEN, CALENDULA OFFICINALIS FLOWER EXTRACT, CARAMEL

COLOR P212, CHAMOMILLA RECUTITA FLOWER EXTRACT, DISODIUM EDTA, ETHYL PARABEN, FRAGRANCE, HONEY EXTRACT, HYDRASTIS CANADENSIS EXTRACT, ISOBUTYLPARABEN, MACROCYSTIS PYRIFERA EXTRACT, METHYLPARABEN, OLEA EUROPAEA FRUIT OIL, PHENOXYETHANOL, POLYISOBUTENE, PROPLYENE GLYCOL, PROPYLPARABEN, RETINYL PALMITATE, SORBITAN OLEATE, SYMPHYTUM OFFICINALE LEAF EXTRACT, TILIA CORDATA FLOWER EXTRACT TOCOPHERYL ACETATE, TRIETHANOLAMINE, WATER



Other Information

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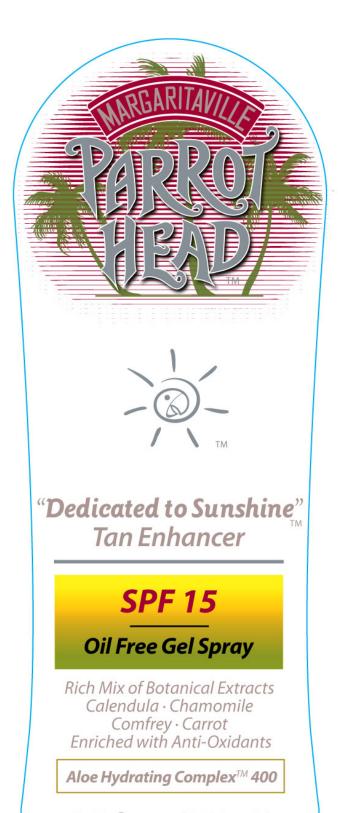
Sun & Skin Care Research, Inc. 851 Greensboro Rd., Cocoa,



FL 32926 1-800-715-3485 Made in USA

white





8.5 fl. oz. (251mL)

PARROT HEAD DEDICATED TO SUNSHINE TAN ENHANCER 15

octinoxate, octisalate spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62802-116
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mL in 100 mL	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5.0 mL in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809 Y72KV36)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CARAMEL (UNII: T9D99G2B1R)	
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)	
ETHYLPARABEN (UNII: 14255EXE39)	
ISOBUTYLPARABEN (UNII: 0 QQJ25X58G)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)	
SORBITAN MONO OLEATE (UNII: 06 XEA2VD56)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:62802-116-85	251 mL in 1 BOTTLE, SPRAY		

Marketing Inform	mation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/11/2012	

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

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