

**PARROT HEAD DEDICATED TO SUNSHINE TAN ENHANCER 8 - octinoxate,
octisalate 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

Octinoxate 4.5%

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 COPOLYMER, 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, ISOBUTYL-PARABEN, MACROCYSTIS PYRIFERA EXTRACT, METHYL-PARABEN, OLEA EUROPAEA FRUIT OIL, PHENOXYETHANOL, POLYISOBUTENE, PROPLYENE GLYCOL, PROPYL-PARABEN, RETINYL PALMITATE, SORBITAN OLEATE, SYMPHYTUM OFFICINALE LEAF EXTRACT, TILIA CORDATA FLOWER EXTRACT TOCOPHERYL ACETATE, TRIETHANOLAMINE, WATER

Other Information

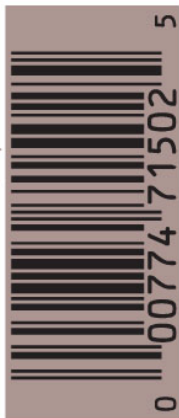
• protect this product from excessive heat and direct sun • for use on skin only.

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Manufactured and Distributed by

Sun & Skin Care Research, Inc.

851 Greensboro Rd., Cocoa,
FL 32926 1-800-715-3485



“Dedicated to Sunshine”TM
Tan Enhancer

SPF 8

Oil Free Gel Spray

Rich Mix of Botanical Extracts
Calendula · Chamomile
Comfrey · Carrot
Enriched with Anti-Oxidants

Aloe Hydrating Complex™ 400

8.5 fl. oz. (251mL)

 white

 SILVER FOIL

PARROT HEAD DEDICATED TO SUNSHINE TAN ENHANCER 8

octinoxate, octisalate spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62802-115	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	4.5 mL in 100 mL	
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)		OCTISALATE	5.0 mL in 100 mL	
Inactive Ingredients				
Ingredient Name				Strength
WATER (UNII: 059QF0KO0R)				
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
BUTYLPARABEN (UNII: 3QP1U3FV8)				
CAMEL (UNII: T9D99G2B1R)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
ETHYLPARABEN (UNII: 14255EXE39)				
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
OLIVE OIL (UNII: 6UYK2W1W1E)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)				
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62802-115-85	251 mL in 1 BOTTLE, SPRAY		
Marketing Information				
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

