

PARROT HEAD DEDICATED TO SUNSHINE OIL 4 - 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
- avoid contact with fabric

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Inactive Ingredients Aloe Barbadensis Leaf Extract, Berthorletia Excelsa Seed Oil, Borago Officinalis Seed Oil, C12-15 Alkyl Benzoate, Cannabis Sativa Seed Oil, Citrus Aurantium Dulcis Peel Oil, Cocos Nucifera Oil, Daucus Carota Sativa Root Extract, Daucus Carota Sativa Seed Oil, Fragrance, Helianthus Annuus Seed Oil, Laureth-4, Olea Europaea Fruit Oil, Persea Gracissima Oil, Polysorbate 80, Prunus Amygdalus Dulcis Oil, Retinyl Palmitate, Tocopheryl Acetate.

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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
Tanning Oil

SPF 6

All Natural Oils

*Rich Mix of Tropical Botanicals
Borage • Hemp • Brazil Nut • Avocado
Natural Tan Enhancers*

Aloe Hydrating ComplexTM 200

8.5 fl. oz. (251 mL)

white

SILVER FOIL

PARROT HEAD DEDICATED TO SUNSHINE OIL 4

octinoxate, octisalate spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62802-114
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 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY8 1Z83H0 X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J6 1HQ)	
COCONUT OIL (UNII: Q9L0 O73W7L)	
CARROT (UNII: L56 Z1JK48B)	
ORANGE OIL (UNII: AKN3KSD11B)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
VITAMIN A PALMITATE (UNII: 1D1K0N0 VVC)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8 X80D2L0)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
LAURETH-4 (UNII: 6HQ855798J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ALMOND OIL (UNII: 66YXD4DKO9)	
CARROT SEED OIL (UNII: 595AO13F11)	
BORAGE OIL (UNII: F8 XAG1755S)	
BRAZIL NUT OIL (UNII: 0G89T29HO6)	
AVOCADO OIL (UNII: 6VNO72PFC1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62802-114-85	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	01/01/2012	

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

Establishment

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

