NO-AD SPF4 DARK TANNING OIL - 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 3.0% Octisalate 2.0%

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

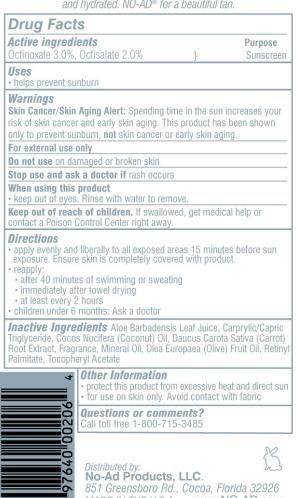
- apply evenly and liberally to all exposed areas 15 minutes before sun exposure. Ensure skin is completely covered with product.
- reapply after 40 minutes of swimming or sweating, immediately after towel drying and at least every 2 hours
- children under 6 months: Ask a doctor

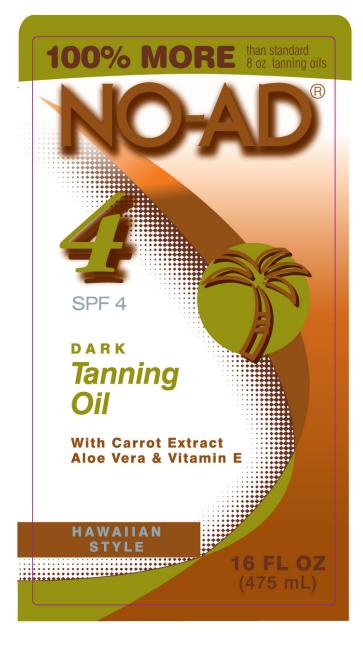
Other Information

- protect this product from excessive heat and direct sun
- for use on skin only
- avoid contact with fabric

Hawaiian Style Dark Tanning Oil is a special formulation enriched with carrot extract and coconut oil to promote the deepest darkest tan.

Moisturizing conditioners aloe vera and vitamin E help keep skin soft and hydrated. NO-AD® for a beautiful tan.





black

UV white R. Screen White Pms 165 PMS 477 PMS 109 PMS 497 dieline

NO-AD SPF4 DARK TANNING OIL

MADE IN THE U.S.A. www.NO-AD.com

octinoxate, octisalate spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62802-206
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3 mL in 100 mL
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	2 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
COCONUT OIL (UNII: Q9L0O73W7L)		
CARROT (UNII: L56Z1JK48B)		
MINERAL OIL (UNII: T5L8T28FGP)		
OLIVE OIL (UNII: 6UYK2W1W1E)		
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)		
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:62802-206-16	475 mL in 1 BOTTLE, SPRAY		

Marketing Infor	mation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	0 1/0 1/20 12	

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

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

Revised: 5/2012 Sun & Skin Care Research, LLC