NO-AD SPF 8 TANNING- octinoxate, 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.

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.

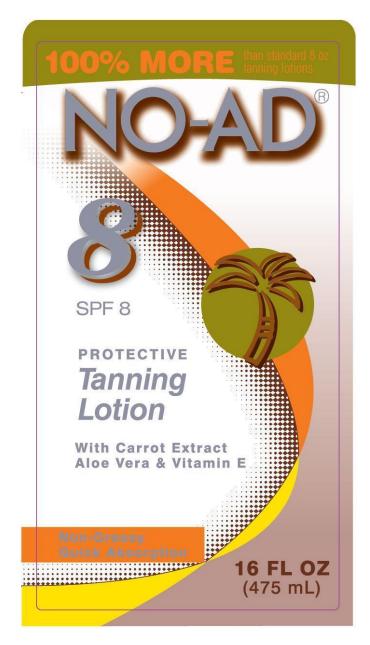
Directions

- 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

carrot extract minimal sun pro	asy lightweight lotion to help promote a d otection. Natural skin nd hydrated. NO-AD®	ark ṫan whíle conditioners	still providing help keep skin		
Drug Fact	s				
Active ingredi Octinoxate 4.5%		}	Purpose Sunscreen		
Uses • helps prevent su	nburn				
risk of skin cance	Aging Alert: Spending r and early skin aging. nburn, not skin cancer only	his product ha	s been shown		
	maged or broken skin		76		
Stop use and as	k a doctor if rash occu	Irs			
When using this • keep out of eyes	product . Rinse with water to re	move.	20		
	:h of children. If swall Control Center right awa		ical help or		
	l liberally to all exposed e skin is completely cov				
 after 40 minute immediately at at least every 2 		ating			
Acrylate Crosspoly Oil, Butylparaben, Sativa (Carrot) Ext	dients Acrylates Cop mer, Aloe Barbadensis L Carborner, Cocos Nucifr ract, Disodium EDTA, Ef (Sunflower) Seed Oil, F Isobutylparaben, Meth Europaea Fruit Oil, Ph Propylparapen, Retiny Tocopheryl Acetate, Ti	eaf Juice, Brass era (Coconut) C hylparaben, Fra lydroxypropyl I ylparaben, Oct enoxyethanol, F I Palmitate, Soi	ica Napus (Canola) ili, Daucus Carota Igrance. Glycerin, Vethylcellulose, yl Palmitate, Olea Propylene Glycol, rbitan Oleate,		
021	Other Information • protect this product from excessive heat and direct sun				
40"0	Questions or comments? Call toll free 1-800-715-3485				
8	Distributed by: No-Ad Product 851 Greensboro F MADE IN THE U.S	Rd., Cocoa, F			



black

UV white R. Screen White Pms 166 PMS 477 PMS 109 PMS 497 dieline

NO-AD SPF 8 TANNING	ŕ				
octinoxate, octisalate lotion					
Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Source)		NDC:62802-210	
Route of Administration	TOPICAL				
Active Ingredient/Active Moi	ety				
Ingredient Name			Basis of Strength		Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)			OCTINOXATE		$4.5\;g$ in $100\;g$
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)			OCTISALATE		5 g in 100 g

Inactive Ingredients					
	Ingredient Nam	ie			Strength
ALOE VERA LEAF (UNII:	ZY81Z83H0X)				
CANOLA OIL (UNII: 331K	BJ17RK)				
BUTYLPARABEN (UNII: 3	QPI1U3FV8)				
CARBOMER HOMOPOL	YMER TYPE C (UNII: 4Q93RCW27E)				
COCONUT OIL (UNII: Q9	L0O73W7L)				
CARROT SEED OIL (UNI	: 595AO13F11)				
EDETATE DISO DIUM (UN	III: 7FLD91C86K)				
VITAMIN A PALMITATE	(UNII: 1D1K0N0VVC)				
ETHYLPARABEN (UNII: 14	4255EXE39)				
GLYCERIN (UNII: PDC6A3	SCOOX)				
SUNFLOWER OIL (UNII:	3W1JG795YI)				
HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN31520P35)				
ISOBUTYLPARABEN (UN	III: 0QQJ25X58G)				
METHYLPARABEN (UNII:	A218C7HI9T)				
ETHYLHEXYL PALMITA	ΓΕ (UNII: 2865993309)				
OLIVE OIL (UNII: 6UYK2)	W1W1E)				
PHENOXYETHANOL (UN	II: HIE492ZZ3T)				
PROPYLENE GLYCOL (U	JNII: 6 DC9 Q 16 7 V3)				
ALPHATOCOPHEROL	ACETATE (UNII: 9E8X80D2L0)				
SORBITAN MONOOLEA	TE (UNII: 06 XEA2VD56)				
TROLAMINE (UNII: 903K	93S3TK)				
WATER (UNII: 059QF0KO	0 R)				
Packaging					
# Item Code	Package Description	Marketing	Start Date	Marketing	End Date
1 NDC:62802-210-16	475 g in 1 BOTTLE				
	0				
Marketing Inform	mation				
Marketing Category	Application Number or Monog	raph Citation	Marketing Start	Date Market	ting End Da
OTC monograph not final	part352		0 1/0 1/20 12		

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

Establishment

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Name	Address	ID/FEI	Business Operations
Sun & Skin Care Research, LLC		849772207	manufacture(62802-210)

Revised: 3/2014

Sun & Skin Care Research, LLC