

**ALOE UP DARK TANNING OIL SPF 4- octinoxate and oxybenzone spray**  
**Prime Packaging, Inc.**

*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.*

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**Active ingredients**

Octinoxate 2 %, and Oxybenzone 2 %

**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.

**When using this product** keep out of eyes. Rinse with water to remove. Keep away from face to avoid breathing it. Contents under pressure - do not puncture or incinerate. Do not store at temperatures above 120 °F

**Stop use and ask a doctor if** rash occurs.

**Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away.

**Flammable:** Do not use near heat, flame or while smoking.

**Directions**

- spray liberally and spread by hand 15 minutes before sun exposure
- hold container 4 to 6 inches from the skin to apply
- do not spray directly into face. Spray on hands then apply to face.
- do not apply in windy conditions
- use in well-ventillated area
- reapply:
  - after 80 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours
- children under 6 months: Ask a doctor

**Inactive Ingredients**

Acrylates/Octylacrylamide Copolymer, Aloe Barbadensis Extract, Ascorbic Acid, C12-15 Alkyl

Benzoate, Castor Oil, Cocos Nucifera (Coconut) Oil, Fragrance (Parfum), Mineral Oil, Retinyl Palmitate, SD Alcohol 40-B (Alcohol Denat.), Tocopheryl Acetate

### Other information

- protect this product from excessive heat and direct sun
- avoid spraying on fabrics - could cause discoloration

Questions or Comments?

Call toll free 1-800-950-2563 - [www.aloeup.com](http://www.aloeup.com)

### PRINCIPAL DISPLAY PANEL - 177 mL Can Label

The image shows the principal display panel of a 177 mL can of Aloe Up Dark Tanning Oil. The label is gold and brown with a central logo of an aloe vera plant. Text on the label includes 'Aloe Up.', 'DARK TANNING OIL', 'SPF 4 CONTINUOUS SPRAY SUNSCREEN', 'MOISTURE RICH FORMULA', 'WATER RESISTANT (80 MINUTES)', 'VITAMIN A, C & E', and '6 FL. OZ. (177 mL)'. A 'Drug Facts' panel is located on the right side of the label, containing information on active ingredients, uses, warnings, directions, and inactive ingredients. A barcode is visible in the bottom right corner.

Indulge yourself with a touch of the tropics. Enriched with aloe vera and coconut oil, this dry oil moisturizes and nourishes your skin to create that golden tan.

Drug Facts	
<b>Active Ingredients</b>	<b>Purpose</b>
Octinoxate 2% Oxybenzone 2%	Sunscreen
<b>Uses</b>	
• helps prevent sunburn	
<b>Warnings</b>	
<b>Skin Cancer/Skin Aging Alert:</b> 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.	
<b>For external use only</b>	
Do not use on damaged or broken skin	
When using this product keep out of eyes. Rinse with water to remove. Keep away from face to avoid breathing it. Contents under pressure - do not puncture or incinerate. Do not store at temperatures above 120°F	
Stop use and ask a doctor if rash occurs	
Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.	
Flammable: Do not use near heat, flame or while smoking.	
<b>Directions</b>	
• spray liberally and spread evenly by hand 15 minutes before sun exposure.	
• hold container 4 to 6 inches from the skin to apply	
• do not spray directly into face. Spray on hands then apply to face.	
• do not apply in windy conditions	
• use in a well-ventilated area	
• reapply:	
• after 80 minutes of swimming or sweating	
• immediately after towel drying	
• at least every 2 hours	
• children under 6 months: Ask a doctor	
<b>Inactive Ingredients</b>	
Acrylates/Octylacrylamide Copolymer, Aloe Barbadosis Extract, Ascorbic Acid (Vitamin C), C12-15 Alkyl Benzoate, Castor Oil, Cocos Nucifera (Coconut) Oil, Fragrance, Mineral Oil, Retinyl Palmitate (Vitamin A), SD Alcohol 40-B, Tocopheryl Acetate (Vitamin E)	
<b>Other Information</b>	
• protect this product from excessive heat and direct sun	
• avoid spraying on fabrics - could cause discoloration.	
<b>Questions or Comments?</b>	
Call toll free 1-800-950-2563 • <a href="http://www.aloeup.com">www.aloeup.com</a>	

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Manufactured for: Aloe Up  
Minneapolis, MN 55344

79385 62100 1

Aloe Up  
DARK

TANNING  
 OIL  
 SPF  
 4  
 CONTINUOUS SPRAY  
 SUNSCREEN  
 MOISTURE  
 RICH FORMULA  
 WATER RESISTANT  
 (80 MINUTES)  
 VITAMIN A, C & E  
 6 FL OZ (177 mL)

**ALOE UP DARK TANNING OIL SPF 4**

octinoxate and oxybenzone spray

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13630-0041
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	16.6 mg in 1 mL
<b>OXYBENZONE</b> (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	16.6 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>CASTOR OIL</b> (UNII: D5340Y2I9G)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	

**Product Characteristics**

<b>Color</b>	yellow	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	

**Contains****Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0041-4	177 mL in 1 CAN; Type 0: Not a Combination Product	01/05/2009	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/05/2009	

**Labeler** - Prime Packaging, Inc. (805987059)**Registrant** - Prime Packaging, Inc. (805987059)**Establishment**

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0041) , analysis(13630-0041)

**Establishment**

Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	label(13630-0041) , pack(13630-0041)

Revised: 1/2020

Prime Packaging, Inc.