SUNTONE BROAD SPECTRUM SPF 4- octinoxate spray
Prime Enterprises, 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.

Active ingredients

Octinoxate 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.

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.

Directions

- apply liberally 15 minutes before sun exposure.
- do not spray directly into face. Spray on hands then apply to face
- reapply:
  - after 80 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hour
- children under 6 months: ask a doctor.

Inactive Ingredients

Aloe Barbadensis Extract, Cocos Nucifera (Coconut) Oil, Fragrance (Parfum), Mineral Oil (Paraffinum Liquidum), Propylparaben, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Tocopheryl Acetate

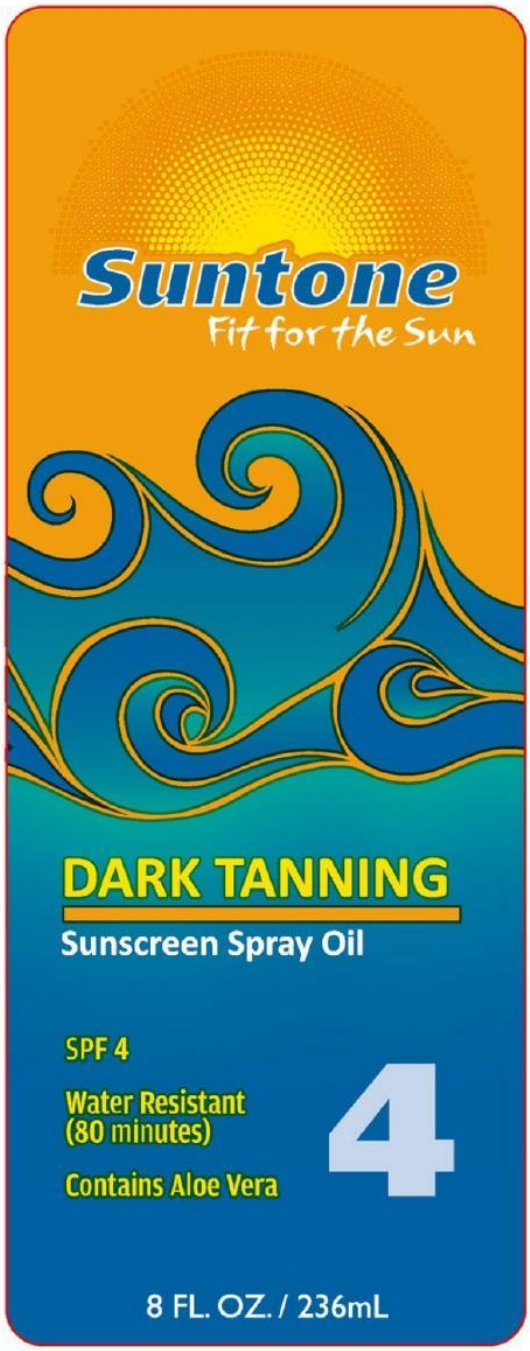
Other information

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

Questions or Comments?

Biocycle Laboratories, Inc.
16363 NW 49 Avenue
Miami, FL 33014

PRINCIPAL DISPLAY PANEL - 236 mL Bottle Label



Drug Facts

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0 87524 96012 6

Distributed by: Biocycle Laboratories, Inc. | Miami, FL 33014
MADE IN USA

Suntone

Fit for the Sun

DARK TANNING

Sunscreen Spray Oil

SPF 4

Water Resistant

(80 Minutes)

4

Contains Aloe Vera

8 FL. OZ./236mL

SUNTONE BROAD SPECTRUM SPF 4

octinoxate spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0098
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	16.7 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
COCONUT OIL (UNII: Q9L0O73W7L)	
MINERAL OIL (UNII: T5L8T28FGP)	
ALOE VERA FLOWER (UNII: 575DY8C1ER)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ALMOND OIL (UNII: 66YXD4DKO9)	
JOJOBA OIL (UNII: 724GKU717M)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58443-0098-4	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/18/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/18/2013	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0098) , pack(58443-0098) , manufacture(58443-0098) , analysis(58443-0098)