

**SUN SCREEN- octinoxate, octisalate, oxybenzone, titanium dioxide lotion  
Webb Business Promotions**

*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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**2oz SPF 30 Sunscreen Lotion**

**Purpose**

**Purpose**

Sun Screen

**Drug Facts**

Octinoxate 7.0%

Octisalate 4.0%

Titanium Dioxide 4.0%

Benzophenone 3.0%

**Directions**

Apply to all exposed skin prior to sun exposure. Reapply as needed especially after swimming or perspiring. Consult a physician before using on children under 6 months.

**Warnings**

**FOR EXTERNAL USE ONLY**

Avoid contact with eyes.

Keep out of reach of children.

**Inactive Ingredients**

**SPF 30 Sunscreen Lotion- 2oz ASI: 95838**

# SPF 30 SUNSCREEN

**Drug Facts**      Made in China

<b>Active Ingredients:</b>	<b>Purpose</b>
Octinoxate - (7%).....	Sunscreen
Octisalate - (4%).....	Sunscreen
Titanium dioxide - (4%).....	Sunscreen
Oxybenzone - (3%).....	Sunscreen

**Directions:** Apply to all exposed skin prior to sun exposure. Reapply as needed especially after swimming or perspiring. Consult a physician before using on children under the age of 6 months.

**Warnings: FOR EXTERNAL USE ONLY**

Avoid contact with eyes  
Keep out of reach of children.

**INACTIVE INGREDIENTS:** WATER, ISOPROPYL MYRISTATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, CETEARYL ALCOHOL, GLYCERIN, C12-15 ALKYL BENZOATE, CETETH-25, GLYCERYL STEARATE, FRAGRANCE, DMDM HYDANTOIN, METHYL PARABEN, PROPLYPARABEN.

**2 oz**      Asi: 95838

## SUN SCREEN

octinoxate, octisalate, oxybenzone, titanium dioxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70445-156
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4 g in 100 g
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 g in 100 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4 g in 100 g
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZ ONE - UNII:95OOS7VE0Y)	OXYBENZONE	3 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)	
<b>CETETH-25</b> (UNII: 5KLY4IOG20)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE</b> (UNII: FJ1H6M2JG9)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70445-156-01	28.34 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/11/2009	

## Marketing Information

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

**Labeler** - Webb Business Promotions (154445647)

## Establishment

Name	Address	ID/FEI	Business Operations
Webb Business Promotions		154445647	manufacture(70445-156)