

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.

1oz SPF 30 Sunscreen Lotion

Purpose

Purpose

Sun Screen

Drug Facts

Octinoxate 7.0%

Octisalate 4.0%

Titanium Dioxide 4.0%

Benzophenone 3.0%

Directions

Warnings

Inactive Ingredients

SPF 30 Sunscreen Lotion-1oz ASI95838

Made in China

SPF 30 SUNSCREEN LOTION - 1oz ASI 95838

Drug Facts Made in China

Active Ingredients:	Purpose
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.

SUN SCREEN

octinoxate, octisalate, oxybenzone, titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70445-158
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DMDM HYDANTOIN (UNII: BYR0546TOW)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)
CETETH-25 (UNII: 5KLY4IOG20)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)
GLYCERIN (UNII: PDC6A3C0OX)
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
WATER (UNII: 059QF0K00R)
METHYLPARABEN (UNII: A2I8C7HI9T)

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70445-158-01	5 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(70445-158)