

5298 SUNSCREEN- octinoxate, octisalate, oxybenzone, titanium dioxide lotion
Innovation Specialties

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.

5298 sunscreen

Drug Facts

Active Ingredient

Octinoxate 7.5 %

Octisalate 2.0 %

Oxybenzone 4.0 %

Titanium Dioxide 2.5%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures(see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

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 products is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure.
- reapply:
 - after 40 minutes of swimming and sweating
 - immediately after towel drying
 - at least every 2 hours
- **Sun Protection Measure.** ☐Spending time in the sun increases your skin risk of cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 higher and

other sun protection measures including:

- limit time in the sun, especially from 10 a.m.-2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Inactive ingredients

Water, C12-15 Alkyl Benzoate, Cetearyl Alcohol, Glycerin, Glyceryl Stearate, Myristyl Propionate, Propylene Glycol Dioleate, Cetareth-25, PEG-9 Dimethicone, Xanthan Gum, Disodium EDTA, Fragrance.

Other information

- protect this product from excessive heat and direct sun

DIN 02448890

***Questions or Comments? Made in China
for Innovation line. Los Angeles CA 90066
Questions? Call: 1-855-755-5346***

Broad Spectrum SPF30 Lotion

Packaging

Broad Spectrum SPF30 Sunscreen Lotion
NetWt 60ml/2.0oz

Drug Facts		60ml/2.0oz
Active Ingredient		Purpose
Octinoxate 7.5%	}	Sunscreen
Octisalate 2.0%		
Oxybenzone 4.0%		
Titanium Dioxide 2.5%		
Uses		
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Other information		
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NDC:71368-206-02 DIN 02448890 Made in China for Innovation line. Los Angeles CA 90066 Questions or Comments? Call:1-855-755-5346		

5298 SUNSCREEN

octinoxate, octisalate, oxybenzone, titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76138-206
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.0 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4.0 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MYRISTYL PROPIONATE (UNII: P59053E7NJ)	
PROPYLENE GLYCOL DIOLEATE (UNII: 84T0LSN7U6)	
CETEARETH-25 (UNII: 8FA93U5T67)	
PEG-9 DIMETHICONE (400 CST) (UNII: 9OZ27X065D)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	COCONUT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76138-206-02	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/15/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/15/2017	

