5281 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.

5281 sunscreen

Drug Facts

Active ingredient

Octinoxate 7.5%
Octisalate 2%
Oxybenzone 4%
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 product 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 or sweating
•immediately after towel drying
•at least every 2 hours
•**Sun Protection Measure.** Spending time in the sun increases your risk of skin 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, Ceteareth-25, PEG-9 Dimethicone, Xanthan Gum, Disodium EDTA, Fragrance.

Other information

•protect this product from excessive heat and direct sun

DIN 02448890

Made in China for Innovation line.

Los Angeles CA 90066

Questions or Comments?

Call:1-855-755-5346

Broad Spectrum SPF30 Lotion

Packaging

Broad Spectrum SPF30 Sunscreen Lotion
Net Wt. 15ml/0.5oz

Drug Facts

Active Ingredient	Purpose
Octinoxate 7.5% Octisalate 2% Oxybenzone 4% Titanium Dioxide 2.5%	Sunscreen

Peel here for continued drug facts ▼

Drug Facts (continued)

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5281 SUNSCREEN

octinoxate, octisalate, oxybenzone, titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76138-207
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 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4 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: 059QF0KO0R)	
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:76138-207-05	15 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2017	

Labeler - Innovation Specialties (030837314)

Revised: 8/2017 Innovation Specialties