

5283 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.

5283 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 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, 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 30ml/1.0oz

Drug Facts

Active Ingredient		Purpose
Octinoxate	7.5%	} Sunscreen
Octisalate	2.0%	
Oxybenzone	4.0%	
Titanium dioxide	2.5%	

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, Cetareth-25, PEG-9 Dimethicone, Xanthan Gum, Disodium EDTA, Fragrance.

Other information

- protect this product from excessive heat and direct sun

NDC: 76138-205-01 DIN 02448890
Made in China for Innovation line.
Los Angeles CA 90066
Questions or Comments?
Call: 1-855-755-5346

octinoxate, octisalate, oxybenzone, titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76138-205
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: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	2 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	4 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	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 DIOLATE (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:76138-205-01	30 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 mono graph not final	part352	05/15/2017	

