

SPF30 SUNSCREEN- octisalate, octisalate, oxybenzone lotion
Shanghai Mengna Personal Care Co., Ltd

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.

SPF30 SUNSCREEN LOTION

Drug Facts

Active Ingredients:

Octinoxate 7.5%, Octisalate 2.0%, Oxybenone 4.0% Titanium Dioxide 2.5%

Purpose

Sunscreen

Uses

- Helps prevent sunburn

WARNINGS:

Skin Cancer/ Sking Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer and early skin aging.
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 generously & evenly before sun exposure.Reapply as needed or after towel drying, swimming, or sweating. Ask doctor before using on children under 6 months.

Inactive ingredients

Water, Cetearyl Alcohol, Xanthan Gum, C12-15 Alkyl Benzoate, Myristyl Propionate, Propylene Glycol, Glyceryl Stearate Citrate, Disodium EDTA, Iodopropynyl Butylcarbamate, DMDM Hydantoin, Fragrance.

Other information

Protect this product from excessive heat and direct sun

Questions or Comment?

Call toll free 1-888-543-0938

Distributed By:

Event Blossom - Tustin, CA 92780 Made in China

Package Labeling:

SPF - 30 SUNSCREEN

Drug Facts

30ml/1fl.oz

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Purpose

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Titanium Dioxide 2.5%Sunscreen

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SPF30 SUNSCREEN

octisalate, octisalate, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71642-016
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	20 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	40 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

XANTHAN GUM (UNII: TTV12P4NEE)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MYRISTYL PROPIONATE (UNII: P59053E7NJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71642-016-00	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/06/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/06/2017	

Labeler - Shanghai Mengna Personal Care Co., Ltd (526931632)

Establishment

Name	Address	ID/FEI	Business Operations
Shanghai Mengna Personal Care Co., Ltd		526931632	manufacture(71642-016)

Revised: 11/2017

Shanghai Mengna Personal Care Co., Ltd