

SUNSCREEN SPF 30- octinoxate, octisalate, oxybenzone, titanium dioxide lotion
Shanghai Kejing Cleaning Products 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.

SPF 30 Sunscreen Lotion

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Active Ingredients

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

Purpose

Sunscreen

Uses

Helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increase your risk of skin cancer and early skin aging. This products has been shown only to prevent sunburn, not skin cancer or 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

f 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

Representative Label

SPF 30 SUNSCREEN LOTION

Drug Facts	
Active Ingredients	Purpose
Octinoxate 7.5%, Octisalate 2.0%, Oxybenzone 4.0%	
Titanium Dioxide 2.5%	Sunscreen
Uses	
•Helps prevent sunburn	
WARNINGS:	
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For external use only.	
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When using this product keep out of eyes. Rinse with water to remove.	
Stop use and ask a doctor if rash occurs.	
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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	
30ml/1fl.oz	Made in China

SUNSCREEN SPF 30

octinoxate, octisalate, oxybenzone, titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:31190-210
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: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	20 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	40 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.5 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 (UNII: 7FLD91C86K)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:31190-210-20	20 mL in 1 BOTTLE		
2	NDC:31190-210-30	30 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/13/2014	

Labeler - Shanghai Kejing Cleaning Products Co., Ltd (526877847)

Establishment

Name	Address	ID/FEI	Business Operations
Shanghai Kejing Cleaning Products Co., Ltd		526877847	manufacture(31190-210)

Revised: 5/2014

Shanghai Kejing Cleaning Products Co., Ltd