octinoxate, octisalate, oxybenzone, titanium dioxide spray 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.

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 product had been shown only to prevent sunburn,

not skin cancer or 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 1-877-254-2281

Insect repellent active ingredients: soybean oil 3%

SPF30 SUNSCREEN SPRAY

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SPESIO SUNSCREEN SPEAY

Drug Facts 2.0 fl.oz
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octinoxate, octisalate, oxybenzone, titanium dioxide spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:31190-230
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 g	

SOYBEAN OIL (UNII: 241ATL177A) (SOYBEAN OIL - UNII:241ATL177A)	SOYBEAN OIL	3.0 g in 100 g
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	2.0 g in 100 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4.0 g in 100 g
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	2.5 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
XANTHAN GUM (UNII: TTV12P4NEE)			
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)			
MYRISTYL PRO PIO NATE (UNII: P59053E7NJ)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)			
EDETATE DISO DIUM (UNII: 7FLD91C86K)			
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)			
DMDM HYDANTO IN (UNII: BYR0546TOW)			

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	VANILLA	Imprint Code		
Contains				

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:31190-230-01	30 g in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2016	
	2 NDC:31190-230-02	60 g in 1 PACKAGE; Type 0: Not a Combination Product	06/25/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/25/2016	

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

Establishment			
Name	Address	ID/FEI	Business Operations
Shanghai Kejing Cleaning Products Co., Ltd.		526877847	manufacture(31190-230)