SUNSCREEN STICK- octinoxate, zinc oxide, octisalate spray Yuyao Jessie Commodity 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.

SUNSCREEN STICK

Active Ingredient

Octinoxate 3%, Octisalate 3%, Zinc Oxide 1%

Purpose

Sunscreen

Use

• 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 is swallowed, get medical help or contact a Poison Control Center right away.

keep out of reach of children

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

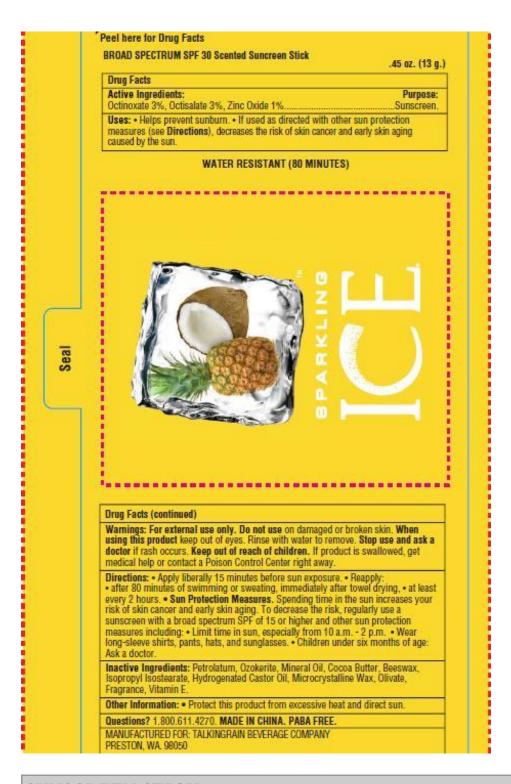
Directions

- Apply liberally 15 minutes before sun exposure. Reapply:
- after 80 minutes of swimming or sweating, immediately after towel drying, at least every 2 hours. Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including: Limit time in sun, especially from 10 a.m. 2 p.m. Wear long-sleeve shirts, pants, hats, and sunglasses. Children under six months of age: Ask a doctor.

Inactive ingredients

Petrolatum, Ozokerite, Mineral Oil, Cocoa Butter, Beeswax, Isopropyl Isostearate, Hydrogenated Castor Oil, Microcrystalline Wax, Olivate, Fragrance, Vitamin E.

lebel



SUNSCREEN STICK

octinoxate, zinc oxide, octisalate spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51414-900
Route of Administration	TOPICAL		

Acti	ve Ingredient/Active Moiety		
	Ingredient Name	Basis of Strength	Strength

Octinoxate (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	Octinoxate	3 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	1 g in 100 g
Octisalate (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	Octisalate	3 g in 100 g

Inactive Ingredients				
Ingredient Name	Strength			
Petrolatum (UNII: 4T6H12BN9U)				
Mineral oil (UNII: T5L8T28FGP)				
Cocoa butter (UNII: 512OYT1CRR)				
Isopropyl isostearate (UNII: C67IXB9Y7T)				
Hydrogenated castor oil (UNII: ZF94AP8MEY)				
Microcrystalline wax (UNII: XOF597Q3KY)				
DECYL OLIVATE (UNII: AQH29B0B3H)				
1.ALPHA.,24S-DIHYDROXYVITAMIN D2 (UNII: 2900 i9 2Z36)				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51414-900-01	10 g in 1 PACKAGE		
2	NDC:51414-900-02	13 g in 1 PACKAGE		
3	NDC:51414-900-03	14 g in 1 PACKAGE		
4	NDC:51414-900-04	15 g in 1 PACKAGE		
5	NDC:51414-900-05	16 g in 1 PACKAGE		
6	NDC:51414-900-06	19 g in 1 PACKAGE		
7	NDC:51414-900-07	20 g in 1 PACKAGE		
8	NDC:51414-900-08	25 g in 1 PACKAGE		
9	NDC:51414-900-09	30 g in 1 PACKAGE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/08/2014	

Labeler - Yuyao Jessie Commodity Co.,Ltd. (529892305)

Establishment				
Name	Address	ID/FEI	Business Operations	
Yuyao Jessie Commodity Co.,Ltd.		529892305	manufacture(51414-900)	

Revised: 5/2014 Yuyao Jessie Commodity Co.,Ltd.