

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

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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, Oliviate, Fragrance, Vitamin E.

label

Peel here for Drug Facts

BROAD SPECTRUM SPF 30 Scented Sunscreen Stick

.45 oz. (13 g.)

Drug Facts

Active Ingredients:

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

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.

WATER RESISTANT (80 MINUTES)

Seal



SPARKLING
ICE

Drug Facts (continued)

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.

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, Oliviate, Fragrance, Vitamin E.

Other Information: • Protect this product from excessive heat and direct sun.

Questions? 1.800.611.4270. **MADE IN CHINA. PABA FREE.**

MANUFACTURED FOR: TALKINGRAIN BEVERAGE COMPANY
PRESTON, WA 98050

SUNSCREEN STICK

octinoxate,zinc oxide,octisalate spray

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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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: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	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: 2900I92Z36)	

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.