SPF15 SUNSCREEN- octinoxate,oxybenzone,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.

SPF 15 sunscreen spray

Active Ingredient

Octinoxate 4.0%
oxybenzone 4.0%
Octisalate 2.0%

Purpose

Sunscreen

Use

Use in well ventilated areas

WARNINGS

For External use only.
Not to be swallowed.Avoid contact with eyes.Discontinue use if signs of irritation or rash appear.Use on children under 6 months of age only with advice of a physician.Keep this and all drug out of the reach of children.In case of accidental ingestion,seek professional assistance or contact a Poision Control Center immediately

keep out of reach of children

Use on children under 6 months of age only with advice of a physician.Keep this and all drug out of the reach of children.

Directions

For best results ,apply 15-30 minutes before sun exposure ,Hold bottle 4-6 inches away from body and apply liberally,spraying slowly and evenly until product is visible on skin.can be applied diredtly to wet skin.reapply after swimming ,excessive perspiration,towel drying or extended sun exposure.Do not apply in windy conditions.Do not spray into face.Spray into hand and apply to the face.Use in well ventilated areas.

Inactive ingredients

ALCOHOL Denat,Glycerin ,Tocopherol ,Fragrance,Deionized WATER ,POLYSORBATE 20

lebel

Drug Fact SPF15 Sunscreen Spray

Active Ingredient	Purpose
Octinoxate 4.0%	Sunscreen
Oxybenzone 4.0%	Sunscreen
Octisalate 2.0%	Sunscreen

Directions: For best results, apply 15-30 minutes before sun exposure. Hold bottle 4-6 inches away from body and apply liberally, spraying slowly and evenly until product is visible on skin. Can be applied directly to wet skin. Reapply after swimming, excessive perspiration, towel drying or extended sun exposure. Do not apply in windy conditions. Do not spray into face. Spray into hand and apply to the face. Use in well ventilated areas.

Warnings: For external use only. Not to be swallowed. Avoid contact with eyes. Discontinue use if signs of irritation or rash appear. Use on children under 6 months of age only with advice of a physician. Keep this and all drug out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poision Control Center immediately.

Caution: Do not use near fire. Store at temerature below 120 F (48 C). Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can ne harmful or fatal.

Inactive Ingredients: Alcohol Denat, Glycerin, Tocopherol, Fragrance, Deionized Water, Polysorbate-20.

SPF15 SUNSCREEN

octinoxate,oxybenzone,octisalate spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51414-600
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	Octinoxate	4 g in 100 g
oxybenzone (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	oxybenzone	4 g in 100 g
Octisalate (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	Octisalate	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
glycerin (UNII: PDC6A3C0OX)	
tocopherol (UNII: R0ZB2556P8)	
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51414-600-01	5 g in 1 PACKAGE		
2	NDC:51414-600-02	7 g in 1 PACKAGE		
3	NDC:51414-600-03	8 g in 1 PACKAGE		
4	NDC:51414-600-04	10 g in 1 PACKAGE		
5	NDC:51414-600-05	12 g in 1 PACKAGE		
6	NDC:51414-600-06	15 g in 1 PACKAGE		
7	NDC:51414-600-07	20 g in 1 PACKAGE		
8	NDC:51414-600-08	25 g in 1 PACKAGE		
9	NDC:51414-600-09	30 g in 1 PACKAGE		
10	NDC:51414-600-10	40 g in 1 PACKAGE		
11	NDC:51414-600-11	50 g in 1 PACKAGE		
12	NDC:51414-600-12	60 g in 1 PACKAGE		
13	NDC:51414-600-13	70 g in 1 PACKAGE		
14	NDC:51414-600-14	80 g in 1 PACKAGE		
15	NDC:51414-600-15	90 g in 1 PACKAGE		
16	NDC:51414-600-16	100 g in 1 PACKAGE		
17	NDC:51414-600-17	120 g in 1 PACKAGE		
18	NDC:51414-600-18	130 g in 1 PACKAGE		
19	NDC:51414-600-19	150 g in 1 PACKAGE		
20	NDC:51414-600-20	160 g in 1 PACKAGE		
21	NDC:51414-600-21	180 g in 1 PACKAGE		
22	NDC:51414-600-22	200 g in 1 PACKAGE		
23	NDC:51414-600-23	220 g in 1 PACKAGE		
24	NDC:51414-600-24	250 g in 1 PACKAGE		
25	NDC:51414-600-25	300 g in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/12/2012	

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

Establishment

Name	Address	ID/FEI	Business Operations
Yuyao Jessie Commodity Co.,Ltd.		529892305	manufacture(51414-600)

Revised: 11/2012 Yuyao Jessie Commodity Co.,Ltd.