

SPF 30 SUNSCREEN- octinoxate oxybenzone octisalate spray
Hangzhou Haorun Technology 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 Spray

Active Ingredient

Octinoxate 6.0%

Oxybenzone 4.0%

Octisalate 5.0%

sunscreen

Use

Protection from the sun's damaging effects.

Warnings

For external use only. Not to be swallowed. Avoid contact with eyes. Discontinue use if signs or 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 and Poison Control Center immediately.

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

Direction

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.

Inactive Ingredient

Alcohol Denat, Glycerin, Tocopherol, Fragrance, Deionized Water, Polysorbate-20

Drug fact SPF30 Sunscreen Spray

Active Ingredient	Purpose
Octinoxate 6.0%.....	Sunscreen
Oxybenzone 4.0%.....	Sunscreen
Octisalate 5.0%.....	Sunscreen

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Made In China
Manufactured by :
Hangzhou Haorun Technology Co., Ltd.

SPF 30 SUNSCREEN

octinoxate oxybenzone octisalate spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57817-300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 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:57817-300-01	10 g in 1 BOTTLE		
2	NDC:57817-300-02	12 g in 1 BOTTLE		
3	NDC:57817-300-03	15 g in 1 BOTTLE		
4	NDC:57817-300-04	20 g in 1 BOTTLE		
5	NDC:57817-300-05	25 g in 1 BOTTLE		
6	NDC:57817-300-06	30 g in 1 BOTTLE		
7	NDC:57817-300-07	35 g in 1 BOTTLE		
8	NDC:57817-300-08	40 g in 1 BOTTLE		
9	NDC:57817-300-09	45 g in 1 BOTTLE		
10	NDC:57817-300-10	50 g in 1 BOTTLE		
11	NDC:57817-300-11	60 g in 1 BOTTLE		
12	NDC:57817-300-12	70 g in 1 BOTTLE		
13	NDC:57817-300-13	80 g in 1 BOTTLE		
14	NDC:57817-300-14	90 g in 1 BOTTLE		
15	NDC:57817-300-15	100 g in 1 BOTTLE		
16	NDC:57817-300-16	110 g in 1 BOTTLE		

17	NDC:57817-300-17	120 g in 1 BOTTLE		
18	NDC:57817-300-18	150 g in 1 BOTTLE		
19	NDC:57817-300-19	180 g in 1 BOTTLE		
20	NDC:57817-300-20	200 g in 1 BOTTLE		
21	NDC:57817-300-21	250 g in 1 BOTTLE		
22	NDC:57817-300-22	300 g in 1 BOTTLE		
23	NDC:57817-300-23	2 g in 1 PACKAGE		
24	NDC:57817-300-23	2 g in 1 PACKAGE		
25	NDC:57817-300-24	3 g in 1 PACKAGE		
26	NDC:57817-300-25	4 g in 1 PACKAGE		
27	NDC:57817-300-26	5 g in 1 PACKAGE		
28	NDC:57817-300-27	6 g in 1 PACKAGE		
29	NDC:57817-300-28	7 g in 1 PACKAGE		
30	NDC:57817-300-29	8 g in 1 PACKAGE		
31	NDC:57817-300-30	9 g in 1 PACKAGE		
32	NDC:57817-300-31	10 g in 1 PACKAGE		
33	NDC:57817-300-32	12 g in 1 PACKAGE		
34	NDC:57817-300-33	15 g in 1 PACKAGE		
35	NDC:57817-300-34	20 g in 1 PACKAGE		
36	NDC:57817-300-35	25 g in 1 PACKAGE		
37	NDC:57817-300-36	30 g in 1 PACKAGE		
38	NDC:57817-300-37	35 g in 1 PACKAGE		
39	NDC:57817-300-38	40 g in 1 PACKAGE		
40	NDC:57817-300-39	45 g in 1 PACKAGE		
41	NDC:57817-300-40	50 g in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/18/2013	

Labeler - Hangzhou Haorun Technology CO.,LTD. (421308583)

Establishment

Name	Address	ID/FEI	Business Operations
Hangzhou Haorun Technology CO.,LTD.		421308583	manufacture(57817-300)

Revised: 3/2013

Hangzhou Haorun Technology CO.,LTD.