

SUNSCREEN- oxybenzone,octinoxate,octisalate lotion
NingBo Huize 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.

71011-004 sunscreen

Active Ingredients

Octinoxate 7.5%,Octisalate 2.0%,Oxybenzone 4.0%

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 products has been shown only to prevent sunburn, not skin cancer or early 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, Stearic acid , Hexadecan-1-ol, Lanolin , Mineral oil, Glyceryl Stearate, POLYSORBATE80, Sorbitan Stearate,Glycerin,DMDM Hydantoin,Frangrance

SPF 30 SUNSCREEN LOTION

Drug Facts

Active Ingredients	Purpose
Octinoxate 7.5%, Octisalate 2.0%, Oxybenzone 4.0%	
Titanium Dioxide 2.5%	Sunscreen

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Other information

Protect this product from excessive heat and direct sun

Questions or Comment ? Call toll free 512-434-0727

Distributed By: festpak - Austin, TX 78732

Made in China

SUNSCREEN

oxybenzone, octinoxate, octisalate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71011-004
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Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	4 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HEXADECANAL (UNII: WQD27655QE)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71011-004-01	100 in 1 BOX	07/18/2018	
1		30 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/18/2018	

Labeler - NingBo Huize Commodity Co.,Ltd. (544434795)**Registrant** - NingBo Huize Commodity Co.,Ltd. (544434795)**Establishment**

Name	Address	ID/FEI	Business Operations
NingBo Huize Commodity Co.,Ltd.		544434795	manufacture(71011-004)

Revised: 7/2018

NingBo Huize Commodity Co.,Ltd.