POLLEN UV PERFECT DAILY SUNSCREEN- titanium dioxide, octinoxate, octisalate, octocrylene cream
NSB 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.

Pollen UV Perfect Daily Sunscreen

Active Ingredients

Octinoxate (Ethylhexyl Methoxycinnamate) (7%)

Octisalate (Ethylhexyl Salicylate) (5%)

Octocyrlene (3%)

Titanium Dioxide (2%)

Purpose

Sunscreen

Keep out of reach of children

Do not swallow. In case of accidental ingestion, seek professional assistance

Warnings

For external use only
Do not use when Your skin is red, inflamed, irritated or painful
When using this product
 Do not apply on other parts of the body
 Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.
 Do not apply directly to wound or open cut.
Stop use and ask doctor if rash or irritation on skin develops and lasts.

Store at room temperature

Uses

Helps prevent sunburn

Directions

• Apply liberally 15 minutes before sun exposure.
• Reapply at least every 2 hours.
• Use a water-resistant sunscreen if swimming or sweating.
• Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 Limit time in the sun, especially from 10 a.m. - 2 p.m.
 Wear long-sleeved shirts, pants, hats, and sunglasses.
Children under 6 months of age: ask a doctor

Inactive Ingredients

Water, Propanediol, Panthenol, Niacinamide, Phenylbenzimidazole Sulfonic Acid, 1,2-Hexanediol, Tromethamine, C14-22 Alcohols, Hydrogenated C6-14 Olefin Polymers, Methylene Bis-Benzotriazolyl Tetramethylbutylphenol, Cetearyl Alcohol, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Glyceryl Stearate, Polyglyceryl-3 Methylglucose Distearate, PEG-100 Stearate, Cyclopentasiloxane, Polyhydroxystearic Acid, Butyrospermum Parkii (Shea Butter), Cyclohexasiloxane, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Stearic Acid, C12-20 Alkyl Glucoside, Dimethicone, Xanthan Gum, Aluminum Hydroxide, Decyl Glucoside, Polyethylene, Pollen Extract, Disodium EDTA, Propylene Glycol, Fragrance

Pollen UV Perfect Daily Sunscreen

POLLEN UV PERFECT DAILY SUNSCREEN

titanium dioxide, octinoxate, octisalate, octocrylene cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70784-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.5 g in 50 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.5 g in 50 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1.5 g in 50 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1 g in 50 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
PANTHENOL (UNII: WV9CM0O67Z)	
NIACINAMIDE (UNII: 25X51I8RD4)	
ENSULIZOLE (UNII: 9YQ9DI1W42)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
TROMETHAMINE (UNII: 023C2WHX2V)	
C14-22 ALCOHOLS (UNII: B1K89384RJ)	
BISOCTRIZOLE (UNII: 8NT850T0YS)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
BEMOTRIZINOL (UNII: PWZ1720CBH)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SHEA BUTTER (UNII: K49155WL9Y)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
C12-20 ALKYL GLUCOSIDE (UNII: K67N5Z1RUA)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
BEE POLLEN (UNII: 3729L8MA2C)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70784-006-02	1 in 1 PACKAGE	09/22/2016	
1	NDC:70784-006-01	50 mL in 1 CONTAINER; 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	09/22/2016	

Labeler - NSB Co., Ltd. (689846922)

Registrant - NSB Co., Ltd. (689846922)

Establishment

Name	Address	ID/FEI	Business Operations
NSB Co., Ltd.		689846922	manufacture(70784-006)

Revised: 1/2019 NSB Co., Ltd.