NAPOLEON PERDIS FOUNDATION STICK BROAD SPECTRUM SPF 15 LOOK 3B - octinoxate, octis alate, titanium dioxide stick Napoleon Perdis Cosmetics, Inc

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.

napoleon PERDIS FOUNDATION STICK BROAD SPECTRUM SPF 15 Look 3B

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Active ingredients

OCTINOXATE 7.5% OCTISALATE 5.0% TITANIUM DIOXIDE 2.0%

Purpose

Sunscreen

Uses

Helps to prevent sunburn.

Warnings

For external use only.

When using this product:

keep out of eyes. Rinse with water to remove.

Stop use and see a doctor if

rash or irritation develops and lasts.

Directions

Apply evenly before sun exposure. Children under 6 months of age: ask a doctor. Reapply as needed or after towel drying, swimming or sweating.

Other information

Moderate sun protection product. Sun alert: limiting sun exposure, wearing protective clothing and using sunscreens may reduce the risks of sun aging, skin cancer, and other harmful effects of the sun. Protect this product from excessive heat and direct sun.

Inactive ingredients:

ETHYLHEXYL PALMITATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, CETYL DIMETHICONE, SILICA, BEESWAX (CERA ALBA), EUPHORBIA CERIFERA (CANDELILLA) WAX

(CANDELILLA CERA), OZOKERITE, NYLON-12, PROPYLENE GLYCOL LAURATE, OCTYLDODECYL NEOPENTANOATE, OCTYLDODECANOL, ALOE BARBADENSIS LEAF EXTRACT, GLYCINE SOJA (SOYBEAN) OIL, TOCOPHEROL, ASCORBYL PALMITATE, TRIETHOXYCAPRYLYLSILANE, CETYL PALMITATE, CAPRYLYL GLYCOL, MAY CONTAIN: MICA, TITANIUM DIOXIDE (CI 77891), IRON OXIDES (CI 77491, CI 77492, CI 77499).

Product Labels



NAPOLEON PERDIS FOUNDATION STICK BROAD SPECTRUM SPF 15 LOOK 3B

octinoxate, octisalate, titanium dioxide stick

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51386-736	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	50 mg in 1 g	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	20 mg in 1 g	

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Inactiv	e Ingredients		

Ingredient Name	Strength
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CANDELILLA WAX (UNII: WL0328HX19)	
NYLON-12 (UNII: 446 U8J075B)	
PROPYLENE GLYCOL MONOLAURATE (UNII: 668Z5835Z3)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0 M87F357)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 ND	C:51386-736-00	1 in 1 CARTON		
1		14 g in 1 CONTAINER		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/12/2013	

Labeler - Napoleon Perdis Cosmetics, Inc (023271316)

Revised: 12/2013 Napoleon Perdis Cosmetics, Inc