SURFERSSKIN SUNSCREEN ZINC - octinoxate, titanium dioxide, zinc oxide stick Skin Alive, 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.

Surfers Skin Sunscreen Zinc

Active Ingredients

Octinoxate 7.5%

Titanium Dioxide 2.35%

Zinc Oxide 4.2%

Purpose

Sunscreen

Uses

Helps prevent sunburn

Higher SPF gives more sunburn protection

Provides high protection against sunburn

Regains SPF after 80 minutes of sweating.

Warnings

For external use only

UV exposure from the sun increases the risk of skin cancer, premature skin aging and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing and using a sunscreen.

When using this product

Keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor

if irritation occurs or rash develops and lasts.

Directions

apply generously 15mins before sun exposure and as needed

Children under 6 months of age: ask a doctor.

Reapply as needed or after towel drying, swimming or sweating.

Inactive Ingredients

Butylated Hydroxytoluene, Castor oil, Fragrance, Hydrogenated castor oil, Iron Oxides, Kaolin, Oleylalcohol, paraffin wax, petroleum jelly, sunflower oil, Talc

SurfersSkin SPF 30+ Sunscreen Zinc gives great protection especially in the snow. Apply liberally to face, nose and lips.

To report a serious adverse event, contact 1-800-332-1088

Expires:

Lot Number:

ww.snowskin.co

DIST. BY Quiver Dist, Bend Oregon, USA 97701

Tested on Snowboarders - Not animals

AS/ANZ STANDARD 2604-1998

Net Wt. 0.30oz (8.5g)

SPF 30+

very water / sweat resistant

broad spectrum

UVA/UVB protection

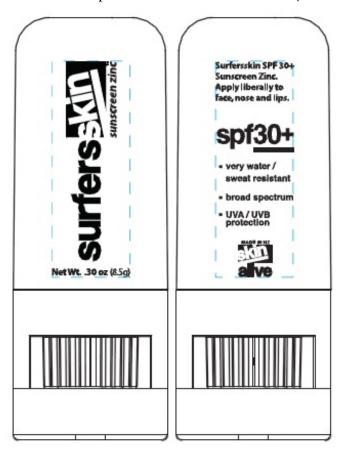
Proven in extreme new zealand conditions

SufersSkin sunscreen Zinc

hands free

Net Wt. 0.30oz (8.5g)

contains no nanoparticles-aminobenzoic acid (PABA) free



Drug Facts

(continued).

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Keep out of reach of children.

www.surfersskin.co

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Net Wt. .30 oz (8.5g)



SURFERSSKIN SUNSCREEN ZINC

octinoxate, titanium dioxide, zinc oxide stick

Product Information

HUMAN OTC DRUG Product Type Item Code (Source) NDC:75916-0636

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength		
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	2.35 g in 100 g		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC OXIDE	4.2 g in 100 g		

Inactive Ingredients		
Ingredient Name	Strength	
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)		
CASTOR OIL (UNII: D5340 Y2I9 G)		
HYDRO GENATED CASTOR OIL (UNII: ZF94AP8MEY)		

IRON (UNII: E1UOL152H7)	
KAOLIN (UNII: 24H4NWX5CO)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
PARAFFIN (UNII: 19 O 0 E 3 H 2 Z E)	
PETROLATUM (UNII: 4T6H12BN9U)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
TALC (UNII: 7SEV7J4R1U)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:75916-0636-1	1 in 1 BOX			
1		8.5 g in 1 TUBE, WITH APPLICATOR			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part352	0 1/27/20 11			

Labeler - Skin Alive, Ltd. (593384746)

Revised: 1/2011 Skin Alive, Ltd.