

NAKED SKIN ONE AND DONE DEEP- spf cream cream
Autumn Harp 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.

Naked Skin One and Done Deep

DRUG FACTS:

Active Ingredients :

Octinoxate 7.5%

Zinc Oxide 3.4%

PURPOSE:

Sunscreen

USES:

Helps prevent sunburn. If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings: 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.

Keo out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

For sunscreen use: 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.

Other Information:

Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients:

Water, Isododecane, Cyclopentasiloxane, Adipic Acid / Neopentyl Glycol Crosspolymer, Lauryl Dimethicone, Aloe Barbadensis Leaf Juice, Titanium Dioxide, Polyglyceryl-6 Polyricinoleate, Dimethicone/Vinyl Dimethicone Crosspolymer, Isononyl Isononanoate, Propylene Glycol, Hydrogenated Polyisobutene, Iron Oxide (CI 77492), Polyglyceryl-2 Isostearate, Glycerin,

Phenoxyethanol, Propanediol, Dimethicone Crosspolymer, Disteardimonium Hectorite, Isopropyl Myristate, Sodium Chloride, Glycyrrhiza Glabra (Licorice) Root Extract, Iron Oxides (CI 77491), Aspergillus Ferment, Xanthan Gum, Isoceteth-10, Iron Oxides (CI 77499), Silica, Isopropyl Titanium Triisostearate, Stearalkonium Hectorite, Triethoxycaprylylsilane, Evodia Rutaecarpa Fruit Extract, Ethoxydiglycol, Cyclotetrasiloxane, Propylene Carbonate, Dimethylcyclosiloxane, Polyhydroxystearic Acid, BHT, Sorbic Acid.

Questions or comments?

CALL TOLL FREE

1-800-784-8722(URBAN)

Package Display Panel



Image Contents

NAKED SKIN ONE AND DONE DEEP			
spf cream cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51514-0348
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	7.5 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	3.4 g in 100 g
Inactive Ingredients			
Ingredient Name			Strength
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)			
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
POLYGLYCERYL-2 MONOISO STEARATE (UNII: 7B8OE71MQC)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			

ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
WATER (UNII: 059QF0KO0R)
ISODODECANE (UNII: A8289P68Y2)
LAURYL TRISILOXANE (UNII: 5OHO78HI1D)
PROPANEDIOL (UNII: 5965N8W85T)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
STEARALKONIUM HECTORITE (UNII: O LX698AH5P)
XANTHAN GUM (UNII: TTV12P4NEE)
ISOPROPYL TITANIUM TRIISO STEARATE (UNII: 949E3KBJ1I)
ISO CETETH-10 (UNII: 1K92T9919H)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
TETRADIIUM RUTICARPUM FRUIT (UNII: Q413WWJ3X9)
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)
ADIPIC ACID/DIGLYCOL CROSSPOLYMER (20000 MPAS) (UNII: R9TPS68K19)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)
ASPERGILLUS FUMIGATUS (UNII: X88DF51T48)
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)
SORBIC ACID (UNII: X045WJ989B)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
CYCLOMETHICONE 4 (UNII: CZ227117JE)
FERRIC OXIDE RED (UNII: 1K09F3G675)
GLYCERIN (UNII: PDC6A3C0OX)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0348-0	40 g in 1 TUBE; Type 0: Not a Combination Product	02/04/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/04/2016	

Labeler - Autumn Harp Inc (064187883)

Establishment

Name	Address	ID/FEI	Business Operations
Autumn Harp Inc.		064187883	manufacture(51514-0348)

