

NAKED SKIN ONE AND DONE, MEDIUM LIGHT- 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, Medium Light

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.

Keep 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, Propylene Glycol, Isononyl Isononanoate, Hydrogenated Polyisobutene, Polyglyceryl-2 Isostearate, Glycerin, Phenoxyethanol, Propanediol,

Dimethicone Crosspolymer, Iron Oxide (CI 77492), Disteardimonium Hectorite, Isopropyl Myristate, Sodium Chloride, Glycyrrhiza Glabra (Licorice) Root Extract, Aspergillus Ferment, Xanthan Gum, Isoceteth-10, Silica, Iron Oxides (CI 77491), Isopropyl Titanium Triisostearate, Stearalkonium Hectorite, Triethoxycaprylylsilane, Iron Oxides (CI 77499), Evodia Rutaecarpa Fruit Extract, Ethoxydiglycol, Cyclotetrasiloxane, Dimethylcyclosiloxane, Propylene Carbonate, Polyhydroxystearic Acid, BHT, Sorbic Acid.

Questions or comments?

CALL TOLL FREE

1-800-784-8722(URBAN)

Principle Display Panel



Image content

NAKED SKIN ONE AND DONE, MEDIUM LIGHT

spf cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51514-0344
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.49 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3.43 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	

SODIUM CHLORIDE (UNII: 451W47IQ8X)
FERRIC OXIDE RED (UNII: 1K09F3G675)
STEARALKONIUM HECTORITE (UNII: O LX698AH5P)
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)
ISODODECANE (UNII: A8289P68Y2)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
ADIPIC ACID/DIGLYCOL CROSSPOLYMER (20000 MPA.S) (UNII: R9TPS68K19)
LAURYL TRISILOXANE (UNII: 5OHO78HI1D)
WATER (UNII: 059QF0K00R)
CYCLOMETHICONE 4 (UNII: CZ227117JE)
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)
GLYCERIN (UNII: PDC6A3C0OX)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
PROPANEDIOL (UNII: 5965N8W85T)
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)
ASPERGILLUS FUMIGATUS (UNII: X88DF51T48)
XANTHAN GUM (UNII: TTV12P4NEE)
ISOCETETH-10 (UNII: 1K92T9919H)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
ISOPROPYL TITANIUM TRIISO STEARATE (UNII: 949E3KBJ1I)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
SORBIC ACID (UNII: X045WJ989B)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
TETRADIIUM RUTICARPUM FRUIT (UNII: Q413WWJ3X9)
ALOE VERA LEAF (UNII: ZY81Z83H0X)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0344-1	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(51514-0344)