

NAKED SKIN ONE AND DONE, MEDIUM- 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

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, 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)

Principle Display Panel

The image shows the back of a Naked Skin Urban Decay sunscreen container. The background is a dark, textured brown. On the left, the words "NAKED SKIN" are written vertically in large, bold, pink letters, with "URBAN DECAY" written vertically in smaller, pink letters to the right of "SKIN". Below this, the "one & done" logo is written in a white, cursive font. Underneath the logo, the text "LONGWEAR COLOR HYBRID COMPLEXION PERFECTOR SUNSCREEN" is printed in white, all-caps. Below that, "BROAD SPECTRUM SPF 20" is printed in white, all-caps. At the bottom left, "40 ml / 1.3 fl. oz." is printed in white. On the right side, there is a block of white text containing product facts, purpose, uses, warnings, directions, and other information. At the bottom right, there is a small logo for "one & done" and the text "Dist by Urban Decay® Cosmetics LLC, Newport Beach, CA 92663, USA. 455 Promenade des Anglais, 06200 Nice, France. Made in USA. urbandecay.com".

PRINCIPLE DISPLAY PANEL

ACTIVE INGREDIENTS:
OCTINOXATE 15%, ZINC OXIDE 3.4%

PURPOSE: Sunscreen

USES: Helps prevent sunburn. If used as directed with other sun protection measures (e.g. t-shirts), 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. to 4 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.

QUESTIONS OR COMMENTS
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455 Promenade des Anglais,
06200 Nice, France. Made in USA.
urbandecay.com

NAKED SKIN ONE AND DONE, MEDIUM

spf cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51514-0345
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
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
CYCLOMETHICONE 5 (UNII: 0THI5PCI0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
ASPERGILLUS FUMIGATUS (UNII: X88DF51T48)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ISOCETETH-10 (UNII: 1K92T9919H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIETHYLENE GLYCOL MONOETHYL ETHER ACETATE (UNII: W5EIM81UBX)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SORBIC ACID (UNII: X045WJ989B)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISOPROPYL TITANIUM TRIISOSTEARATE (UNII: 949E3KBJ1I)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
TETRAIDIUM RUTICARPUM FRUIT (UNII: Q413WWJ3X9)	
WATER (UNII: 059QF0KO0R)	
ISODODECANE (UNII: A8289P68Y2)	

ADIPIC ACID/DIGLYCOL CROSSPOLYMER (20000 MPAS) (UNII: R9TPS68K19)

LAURYL TRISILOXANE (UNII: 5OHO78HI1D)

PROPANEDIOL (UNII: 5965N8W85T)

POLYGLYCERYL-2 MONOISOSTEARATE (UNII: 7B8OE71MQC)

STEARALKONIUM HECTORITE (UNII: O LX698AH5P)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0345-0	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(51514-0345)

Revised: 11/2019

Autumn Harp Inc.