

ALMAY AGE ESSENTIALS CONCEALER SPF 20- octinoxate zinc oxide liquid

Almay, 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.

Almay Age Essentials Concealer SPF 20

Active Ingredients :

Octinoxate: 7.5%

Zinc Oxide 2.4%

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 a rash occurs
- Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control center right away

Directions

- Apply liberally 15 minutes before sun exposure
- Use a water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- Children under 6 months: Ask a doctor.

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 am - 2 pm
- Wear long-sleeved shirts, pants, hats and sunglasses.

Inactive Ingredients

Dimethicone, Polyethylene, Neopentyl Glycol Diheptanoate, Trimethylsiloxysilicate, Polyisobutene,

Route of Administration	TOPICAL
--------------------------------	---------

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	2.4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
BORON NITRIDE (UNII: 2U4T60A6YD)	
SORBITAN TRIOLEATE (UNII: QE6F49RPJ1)	
KAOLIN (UNII: 24H4NWX5CO)	
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HYALURONIC ACID (UNII: S270N0TRQY)	
TRISILOXANE (UNII: 9G1ZW13R0G)	
ISOSTEARYL BEHENATE (UNII: NA95U012OW)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
DIMETHICONE/BIS-ISOBUTYL PPG-20 CROSSPOLYMER (UNII: O4I3UFO6ZF)	
ISOPROPYL TITANIUM TRIISOSTEARATE (UNII: 949E3KBJ1I)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
SODIUM CHONDROITIN SULFATE (PORCINE; 5500 MW) (UNII: H5BJH23Z9A)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
SORBIC ACID (UNII: X045WJ989B)	
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CERESIN (UNII: Q1LS2UJO3A)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
TRIMETHYLSILOXYLICATE (M/Q 0.8-1.0) (UNII: 25LXE464L2)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0311-0708-13	3.8 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/16/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/16/2016	

Labeler - Almay, Inc. (064988652)

Establishment

Name	Address	ID/FEI	Business Operations
REVLON, INC.		809725570	manufacture(0311-0708)

Revised: 12/2016

Almay, Inc.