

ALMAY ANTI AGING LIP CARE SPF 20- octinoxate, octisalate, homosalate, oxybenzone, avobenzone lipstick

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 Anti Aging Lip Care SPF 20

Active Ingredients :

Octinoxate - 7.5%

Octisalate 5%

Homosalate 5.0%

Oxybenzone 5.0%

Avobenzone 3%

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

Polybutene, Diisostearyl Malate, Bis-Diglyceryl Polyacyladipate-2, Ozokerite, Octyldodecyl Neopentanoate, Petrolatum, Polyethylene, C10-30 Cholesterol/Lanosterol Esters, Synthetic Fluorphlogopite, Silica, Paraffin, Butyrospermum Parkii (Shea) Butter, Argania Spinosa Kernel Oil, Dimethicone, Synthetic Wax, Nylon-12, Cocos Nucifera (Coconut) Oil, Ethylhexyl Palmitate, Cetearyl Ethylhexanoate, Mica, Flavor, Tocopheryl Acetate, Diisopropyl Dimer Dilinoleate, Menthol, Titanium Dioxide (CI 77891), Benzoic Acid, BHT, Phospholipids, Sorbitan Isostearate, Sodium Saccharin, Silica Dimethyl Silylate, Portulaca Pilosa Extract, Aqua/Water/Eau, Caprylyl Glycol, Butylene Glycol, Phenoxyethanol, Sucrose Cocoate, Hyaluronic Acid, Sodium Chondroitin Sulfate, Atelocollagen, Tocopherol, Sodium Hyaluronate, Hexylene Glycol, Soluble Collagen, Tripeptide-29, Palmitoyl Tripeptide-38, Methyl Acetylglycyrhethinoyl Hydroxyprolinate

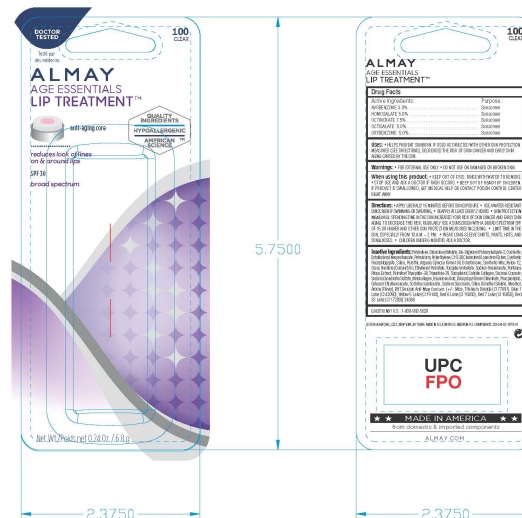
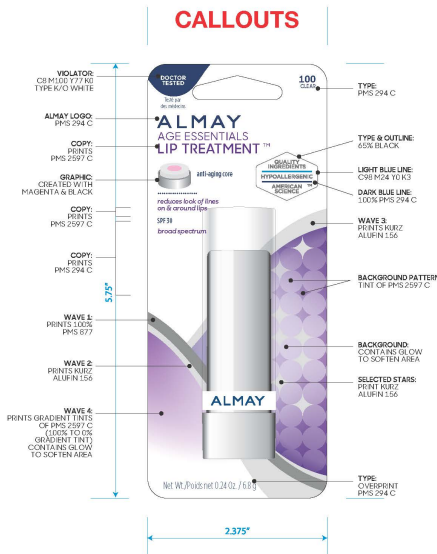
Principal Display Panel

Almay

Almay Anti Aging Lip Care SPF 20

0.24 Oz. / 6.8 g

ALMAY AGE ESSENTIALS LIP TREATMENT (US/SPF)
NON-NEW CARD
YL00322 / 9718-01
2.375" W x 5.75" H



ENLARGED 175% FOR PROOFREADING

100 CLEAR

ALMAY AGE ESSENTIALS LIP TREATMENT™

Drug Facts

Active Ingredients:	Purpose:
AVOBENZONE 0.10%	Sunscreen
HOMOSALATE 0.0%	Sunscreen
OCTYLDIODECYL SEBACATE 7.0%	Sunscreen
OCTYLSALATE 5.0%	Sunscreen
AVOBENZONE 5.0%	Sunscreen

Directions: • APPLY USUALLY 15 MINUTES BEFORE SUN EXPOSURE. • USE A WATER RESISTANT SUNSCREEN IF SWIMMING OR SWEATING. • REAPPLY AT LEAST EVERY 2 HOURS. • 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 OF 15 OR HIGHER AND OTHER SUN PROTECTION MEASURES INCLUDING: • LIMIT TIME IN THE SUN, ESPECIALLY FROM 10 AM - 3 PM. • WEAR LONG-SLEEVE SHIRTS, PANTS, HATS, AND SUNGLASSES. • CHILDREN UNDER 6 MONTHS ASK A DOCTOR.

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 PRODUCT IS SWALLOWED, GET MEDICAL HELP OR CONTACT POISON CONTROL, CENTER FOR DISEASE CONTROL.

Inactive Ingredients: Polybutene, Diisostearyl Malate, Bis-Diglyceryl Polyacyladipate-2, Ozokerite, Octyldodecyl Neopentanoate, Petrolatum, Polyethylene, C10-30 Cholesterol/Lanosterol Esters, Synthetic Fluorphlogopite, Silica, Paraffin, Argania Spinosa Kernel Oil, Dimethicone, Synthetic Wax, Nylon-12, Cocos Nucifera (Coconut) Oil, Ethylhexyl Palmitate, Tocopheryl Acetate, Sodium Hyaluronate, Portulaca Pilosa Extract, Phenoxyethanol, Tripeptide-29, Tripeptide-38, Tocopherol, Soluble Collagen, Sucrose Cocoate, Sodium Chondroitin Sulfate, Atelocollagen, Hyaluronic Acid, Disopropyl Dimer Dilinoleate, Phospholipids, Benzoic Acid, BHT, Sorbitan Isostearate, Sodium Saccharin, Silica Dimethyl Silylate, Menthol, Aqua/Water/Eau, Caprylyl Glycol, Butylene Glycol, Phenoxyethanol, Sucrose Cocoate, Hyaluronic Acid, Sodium Chondroitin Sulfate, Atelocollagen, Tripeptide-29, Palmitoyl Tripeptide-38, Methyl Acetylglycyrhethinoyl Hydroxyprolinate.

QUESTION? U.S.: 1-800-992-9629

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UPC: 309979718016

REVLON ART RERELEASE: 6/15/2016

BRAND: ALMAY FRANCHISE: AGE ESSENTIALS

DESCRIPTION: ALMAY AGE ESSENTIALS LIP TREATMENT (US/SPF) NON-NEW COMPONENT: CARD PROGRAM#: 16-8618 PROJECT#: YL00322

STOCK#: 221434-02 MLI#: 24088 PRODUCT#: 9718-01

SIZE: 2.375" W X 5.75" H

FILE NAME: YL00322_Almay_Prune_CARD-US_Non-New_CS5_Rerelease_6-15-16.ai

SUBSTRATE IS WHITE

- BLUE LOGO, LINE, TYPE & DOCTOR TESTED FLAG PRINT: 100% Pantone 294 C
- PURPLE TYPE PRINTS: 100% Pantone 2597 C
- STAR/CIRCLE PATTERN PRINTS: VARIOUS TINTS OF PMS 2597
- WAVE 1 PRINTS: 100% PMS 877
- WAVE 2, WAVE 3, & SELECT STARS PRINT: RUBY ALUMIN 156 METALLIC SILVER FOIL
- WAVE 4 PRINTS: VARIOUS TINTS OF PMS 2597
- LIGHT BLUE LINE PRINTS: LIBERTY BLUE
- GRAY TYPE PRINTS: 65% BLACK

- PRODUCT GRAPHIC PRINTS: TINTS OF BLACK & MAGENTA
- BLACK TEXT, LOGO, RULES AND UPC PRINT: 100% BLACK
- CYAN RULES REPRESENT DIE AND MEASUREMENTS: 100% CYAN
- CYAN DASHED RULES REPRESENT LIVE AREA: DO NOT PRINT

ALMAY ANTI AGING LIP CARE SPF 20

octinoxate, octisalate, homosalate, oxybenzone, avobenzene lipstick

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0311-0709

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
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POLYBUTENE (1400 MW) (UNII: 1NA5A09GH7)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
BIS-DIGLYCERYL POLYACYLADIPATE-2 (UNII: 6L246LAM9T)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
PETROLATUM (UNII: 4T6H12BN9U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
C10-30 CHOLESTEROL/LANOSTEROL ESTERS (UNII: 137SL7IL0Y)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)	
TRIMETHYLSILOXYSILICATE (M/Q 0.8-1.0) (UNII: 25LXE464L2)	
PARAFFIN (UNII: I9O0E3H2ZE)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SHEA BUTTER (UNII: K49155WL9Y)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SYNTHETIC WAX (1200 MW) (UNII: Q3Z4BCH099)	
NYLON-12 (UNII: 446U8J075B)	
COCONUT (UNII: 3RT3536DHY)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CETEARYL ETHYLHEXANOATE (UNII: 9M64UO4C25)	
MICA (UNII: V8A1AW0880)	
MENTHOL (UNII: L7T10EIP3A)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
WATER (UNII: 059QF0KO0R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SUCROSE COCOATE (UNII: 3H18P0UK73)	
HYALURONIC ACID (UNII: S270N0TRQY)	
SODIUM CHONDROITIN SULFATE (PORCINE; 5500 MW) (UNII: H5BJH23Z9A)	
TOCOPHEROL (UNII: R0ZB2556P8)	

CERESIN (UNII: Q1LS2UJO3A)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0311-0709-01	6.8 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/20/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/20/2016	

Labeler - Almay, Inc. (064988652)

Establishment

Name	Address	ID/FEI	Business Operations
REVLON, INC.		809725570	manufacture(0311-0709)

Revised: 10/2019

Almay, Inc.