

REVLON COLORSTAY PREO AND PROTECT PRIMER- titanium dioxide, zinc oxide, octinoxate primer liquid

Revlon Consumer Products Corp

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.

Revlon Colorstay Prep & Protect Primer / Base

Active Ingredients

Titanium Dioxide 3.6%

Zinc Oxide 9.0%

Octinoxate 7.5%

Purpose

Sunscreen

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

Apply liberally 15 minutes before sun exposure.

Reapply at least every 2 hours.

Use a water resistant sunscreen when swimming or sweating

Sun Protection Measures

Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10a.m - 2p.m.
- wear long -sleeved shirts, pants, hats and sunglasses.
- children under 6 months: Ask a doctor

Inactive Ingredients

CYCLOPENTASILOXANE; AQUA/WATER/EAU; ZINC OXIDE ; ETHYLHEXYL METHOXYCINNAMATE; TRIMETHYLSILOXYSILICATE; GLYCERIN; TITANIUM DIOXIDE;

PEG-10 DIMETHICONE; PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE; DIMETHICONE; POLYMETHYLSILSESQUIOXANE; HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER]; HEXYL LAURATE; POLYGLYCERYL-4 ISOSTEARATE; PERLITE; DIMETHICONE/PEG-10/15 CROSSPOLYMER; PHENOXYETHANOL; XANTHAN GUM; MAGNESIUM SULFATE; STEARIC ACID; CAPRYLYL GLYCOL; 1,2-HEXANEDIOL; ALUMINA; CITRULLUS LANATUS (WATERMELON) FRUIT EXTRACT]; LENS ESCULENTA (LENTIL) FRUIT EXTRACT; POLYSILICONE-11; PYRUS MALUS (APPLE) FRUIT EXTRACT; IRON OXIDES (CI 77499); TOCOPHERYL ACETATE; SODIUM LACTATE; SODIUM PCA; TETRASODIUM EDTA; ETHYLHEXYL PALMITATE; BUTYLENE GLYCOL; SALICYLIC ACID; SILICA DIMETHYL SILYLATE

Package label for Revlon Colorstay Prep & Protect Primer/Base

Principal Display Panel

REVLON OZONE - COLORSTAY UV PRIMER
FRONT DECO
CF04469 / 8619-01
29mm W x 45mm H

FOR POSITION ONLY
DOES NOT PRINT



ENLARGED 200% FOR PROOFREADING



SUBSTRATE IS WHITE - MATCH APPROVED TARGET WITH BLACK CAP

BLACK TEXT PRINTS:
100% BLACK SILKSCREEN

CYAN RULES REPRESENT DIE AND MEASUREMENTS:
DO NOT PRINT

UPC: N/A

REVLON		ART RE-RELEASE: 09/18/2017
BRAND: REVLON	FRANCHISE: Colorstay	ARTIST: EA
DESCRIPTION: Revlon Colorstay UV Primer Front Deco		
COMPONENT: Front Deco	PROGRAM: N/A	PROJECT: CF04469
STOCK#: 225004-00	MLB: N/A	PRODUCT#: 8619-01
SIZE: 29mm W X 45mm H	SAP: N/A	
FILE NAME: 225004-00_RV_Ozone_CS_UV_Primer_FrontDeco_09-18-17_F1N4e		

REVLON

Colorstay Prep & Protect Primer / Base

REVLON COLORSTAY PREO AND PROTECT PRIMER

titanium dioxide, zinc oxide, octinoxate primer liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10967-652
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
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3.6 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	9 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
EDETATE SODIUM (UNII: MP1J8420LU)	
WATER (UNII: 059QF0KO0R)	
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
LENS CULINARIS FRUIT (UNII: ZYZ076G9JH)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
CYCLOMETHICONE 5 (UNII: 0THF5PC10R)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
PERLITE (UNII: 0SG101ZGK9)	
PEG-12 DIMETHICONE/PPG-20 CROSSPOLYMER (UNII: 965K72OQXO)	
XANTHAN GUM (UNII: TTV12P4NEE)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
ALUMINUM OXIDE (UNII: LM26O6933)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
WATERMELON (UNII: 231473QB6R)	
APPLE (UNII: B423VGH5S9)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10967-652-11	26.6 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/01/2019	

Labeler - Revlon Consumer Products Corp (788820165)**Establishment**

Name	Address	ID/FEI	Business Operations
Revlon, INC.		809725570	manufacture(10967-652)

Revised: 1/2019

Revlon Consumer Products Corp