

REVLON PHOTOREADY INSTA-FIX MAKEUP- titanium dioxide, zinc oxide stick
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 PHOTOREADY INSTA-FIX MAKEUP

Active Ingredients:

Titanium Dioxide 4.3%

Zinc Oxide 2.8

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:

Boron Nitride, Phenyl Trimethicone, Ozokerite, Bis-(C12-14 Alkyl PPG-2) Hexamethylenediurea, Sodium Ascorbyl Phosphate, Niacinamide, Hydrolyzed Oat Flour, Tocopheryl Acetate, Lecithin, Phytosteryl Canola Glycerides, Palmitic Acid, Oleic Acid, Ceramide 3, Tocopherol, Phytosphingosine, Hydrogenated Jojoba Oil, Ceramide 6 II, Cholesterol, Ceramide 1, Alumina, Nylon-12, Triethoxycaprylylsilane, Methicone, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Polyglyceryl-4 Isostearate, Dimethicone Crosspolymer, C12-15 Alkyl Benzoate, Sodium Lauroyl Lactylate, Linoleic

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	2.1 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4.7 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISOHEXADECANE (UNII: 918X10UF1E)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
BORON NITRIDE (UNII: 2U4T60A6YD)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
NIACINAMIDE (UNII: 25X51I8RD4)	
OATMEAL (UNII: 8PI54V663Y)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
PALMITIC ACID (UNII: 2V16EO95H1)	
OLEIC ACID (UNII: 2UMI9U37CP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CERAMIDE 3 (UNII: 4370DF050B)	
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	
HYDROGENATED JOJOBA OIL (UNII: 7F674YQ5SO)	
CERAMIDE 6 II (UNII: F1X8L2B00J)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
CERAMIDE 1 (UNII: 5THT33P7X7)	
ALUMINUM OXIDE (UNII: LM26O6933)	
NYLON-12 (UNII: 446U8J075B)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERYL TRIOLEATE (UNII: O05EC62663)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
SORBIC ACID (UNII: X045WJ989B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10967-631-24	10.35 mL in 1 TUBE; Type 0: Not a Combination Product	09/14/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	09/14/2014	

Labeler - Revlon Consumer Products Corp (788820165)

Establishment

Name	Address	ID/FEI	Business Operations
REVLON, INC.		809725570	manufacture(10967-631)

Revised: 11/2019

Revlon Consumer Products Corp