

CK ONE ALL DAY PERFECTION FACE MAKEUP SPF 20 SUNSCREEN 100 PORCELAIN-titanium dioxide and octinoxate lotion

Coty US LLC

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.

Drug Facts

Active Ingredients

☐ **Active Ingredients**

Titanium Dioxide 4.95%

Octinoxate 3.0%

☐ **Purpose**

Titanium Dioxide }Sunscreen

Octinoxate }Sunscreen

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

☐ **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.

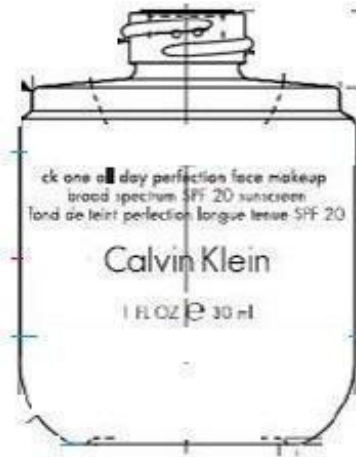
☐ **Directions**

- Apply liberally 15 minutes before sun exposure
- 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 of SPF of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. -2p.m.
 - wear long-sleeve shirts, pants, hats and sunglasses
 - Children under 6 months: ask a doctor

☐ **Inactive Ingredients**

Cyclopentasiloxane, Aqua/Water/Eau, Butylene Glycol, Talc, Cetyl PEG/PPG-10/1 Dimethicone, Trimethylsiloxysilicate, Acrylates Crosspolymer, Ammonium Acrylates Copolymer, BIS-PEG/PPG-14/14 Dimethicone, Polymethyl Methacrylate, Tribehenin, Disteardimonium Hectorite, Laureth-7, Lecithin, Phenoxyethanol, Trihydroxystearin, Chlorphenesin, Triethoxycaprylsilane, Dimethiconol, Parfum/Fragrance, Alcohol Denat., Propylene Carbonate, Xanthan Gum, Glycerin, Disodium Deceth-5 Sulfosuccinate, Tocopheryl Acetate, Parfum/Fragrance, Disodium EDTA, Laureth-30, Sodium PCA,

Urea, Laurtho-4, Sodium Dehydroacetate, Trehalose, Hexylene Glycol, Polyquaternium-51, BHT, Caprylyl Glycol, Triacetin, Sodium Hyaluronate, Pentaerythrityl Tetra-Di-T-Butyl Hydroxyhydrocinnamate, [May Contain: Iron Oxides].



Secondary Artwork

ck one all day perfection face makeup
broad spectrum SPF 20 sunscreen

Drug Facts	
Active Ingredients	Purpose
Titanium dioxide 4.95%	Sunscreen
Ocinoxate 3.0%	Sunscreen
Uses	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> apply liberally 15 minutes before sun exposure 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: <ul style="list-style-type: none"> limit time in the sun, especially from 10 a.m. – 2 p.m. wear long-sleeve shirts, pants, hats, and sunglasses children under 6 months of age: ask a doctor 	
Inactive Ingredients	
cyclopentasiloxane, aqua/water/leau, butylene glycol, talc, cetyl ppg-10/1 dimethicone, trimethylsilyloxy silicate, acrylates crosspolymer, cetearyl ethylhexanoate, magnesium sulfate, dimethicone/vinyl dimethicone crosspolymer, ammonium acrylates copolymer, ▶	

Drug Facts (continued)
bis-peg/ppg-14/14 dimethicone, polymethyl methacrylate, tribehenin, disteardimonium hectorite, laureth-7, lecithin, phenoxyethanol, trihydroxystearin, chlorphenesin, triethoxycaprylylsilane, dimethiconol, parfum/fragrance, alcohol denat., propylene carbonate, xanthan gum, glycerin, disodium deceth-5 sulfosuccinate, tocopheryl acetate, parfum/fragrance, disodium edta, laureth-30, sodium pca, urea, laureth-4, sodium dehydroacetate, trehalose, hexylene glycol, polyquaternium-51, bht, caprylyl glycol, triacetin, sodium hyaluronate, pentaerythrityl tetra-di-n-butyl hydroxyhydrocinnamate, [may contain iron oxides].
Other Information
<ul style="list-style-type: none"> protect this product from excessive heat and direct sun
Questions or Comments?
Call Toll Free 1-800-715-4023



- all day perfection face makeup**
- high-performance foundation that provides ultimate wear, coverage + comfort
 - color + coverage stays true from day to night
 - 24-hour wear
 - oil-free, lightweight formula
 - medium-to-full buildable coverage
 - flawlessly soft + smooth velvet finish
 - dermatologist tested
 - suitable for all skin-types
 - skin is protected from future damage with broad spectrum spf 20 + vitamin e
- usage:** apply lightly and evenly to face and blend.

ck one all day perfection face makeup
broad spectrum SPF 20 sunscreen

Calvin Klein

1 FL OZ 30 ml

99030023028

Shade label



Bottom Label



CK ONE ALL DAY PERFECTION FACE MAKEUP SPF 20 SUNSCREEN 100 PORCELAIN

titanium dioxide and octinoxate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66184-528
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	1.648359 g in 30 mL
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.999 g in 30 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TALC (UNII: 7SEV7J4R1U)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
TRIMETHYLSILOXYLSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
CETEARYL ETHYLHEXANOATE (UNII: 9M64UO4C25)	
MAGNESIUM SULFATE (UNII: DE08037SAB)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
LAURETH-7 (UNII: Z95S6G8201)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TRIHYDROXYSTEARIN (UNII: 06YD7896S3)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
DIMETHICONOL (100000 CST) (UNII: OSA9UP217S)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
LAURETH-30 (UNII: W9D845551A)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
UREA (UNII: 8W8T17847W)	
LAURETH-4 (UNII: 6HQ855798J)	
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	
TREHALOSE (UNII: B8WCK70T7I)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TRIACETIN (UNII: XHX3C3X673)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66184-528-02	1 in 1 BOX		
1	NDC:66184-528-01	30 mL in 1 BOTTLE		
2	NDC:66184-528-03	5 mL in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/01/2014	

Labeler - Coty US LLC (789573201)

Registrant - Coty Inc. (958662223)

Establishment

Name	Address	ID/FEI	Business Operations
Kolmar Korea Co.,Ltd		688732723	manufacture(66184-528)

Revised: 5/2014

Coty US LLC