

CK ONE 3-IN-1 FACE MAKEUP WITH SPF 8 SUNSCREEN 050 IVORY- titanium dioxide and octinoxate liquid

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

Octinoxate 2.0%

Titanium Dioxide 2.5%

Sunscreen

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

Helps prevent sunburn.

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, no skin cancer or early skin aging.

- Apply liberally 15 minutes before sun exposure
- Use a water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- Children under 12 months: ask a doctor

aqua/water/eau, cyclopentasiloxane, neopentyl glycol diethylhexanoate, butylene glycol, hdi/trimethylol crosspolymer, mica, glycerin, vinyl dimethicone/methicone silsesquioxane crosspolymer, peg-10 dimethicone, caprylic/capric triglyceride, disteardimonium hectorite, phenoxyethanol, methyl methacrylate crosspolymer, caprylyl glycol, aluminum dimyristate, triethoxycaprylylsilane, parfum/fragrance, retinyl palmitate, sodium hyaluronate, tocopheryl acetate, silica, disodium stearyl glutamate, ascorbyl glucoside, sorbic acid, alaria esculenta extract, tocopherol, bht, [may contain: iron oxides]

Drug Facts

Active ingredients	Purpose
Octinoxate 2.0%	Sunscreen
Titanium dioxide 2.5%	Sunscreen

Use Helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

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.

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

Directions

For sunscreen use:

- 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

Inactive ingredients

aqua/water, wax, cyclopentasiloxane, hexapentyl diethyl dimethylsilylanthracene, butylene glycol, hydroxyethyl acrylate, polyacrylamide, mica, glycerin, vinyl dimethacrylate/methylacrylate, polyacrylamide crosspolymer, poly-10 dimethicone,

Drug Facts (continued)

caprylic/capric triglyceride, distardimonium heclorin, phenoxymethyl methacrylate, crosspolymer, caprylyl glycol dimethacrylate, triethoxycaprylate, perfume/fragrance, retinyl palmitate, sodium hydroxide, tocopheryl acetate, zinc oxide, ascorbic acid, silica, acetylsalicylic acid, benzophenone, bht, may contain: iron oxides.

Other information

Protect this product from heat and direct sun.

Questions or comments?

Call 1-800-715-4033.

ck
one

3-in-1 face makeup

- daily serum, primer + base makeup all in one
- revolutionary complexion perfecting formula
- creates skin tone + texture
- weightless feel on skin
- 100% waterlocking fresh
- fresh + healthy looking complexion all day
- dermatologist tested, noncomedogenic
- suitable for all skin types
- spf 8, with vitamins a, c, and e
- usage: apply lightly and evenly to entire face and blend.

ck one 3-in-1 face makeup
with SPF 8 sunscreen

Calvin Klein

1 FL. OZ. 30 ml

100% WATER RESISTANT

Made in America
Calvin Klein Cosmetics
One Calvert City, MD 21116
© 2007 Calvin Klein Cosmetics



CK ONE 3-IN-1 FACE MAKEUP WITH SPF 8 SUNSCREEN 050 IVORY

titanium dioxide and octinoxate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66184-401
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.302 g in 30 mL
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.606 g in 30 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
Neopentyl Glycol (UNII: QI80HXD6S5)	
Butylene Glycol (UNII: 3XUS85K0RA)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
Tricaprin (UNII: O1PB8EU98M)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Methyl Methacrylate (UNII: 196OC77688)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Aluminum Dimyristate (UNII: J2KA067N9O)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Vitamin A Palmitate (UNII: 1D1K0N0VVC)	
Hyaluronate Sodium (UNII: YSE9PPT4TH)	
Alpha-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Disodium Stearoyl Glutamate (UNII: 45ASM2L11M)	
Sorbic Acid (UNII: X045WJ989B)	
Alaria Esculenta (UNII: EJ9JK8J58D)	
Tocopherol (UNII: R0ZB2556P8)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66184-401-02	1 in 1 BOX		
1	NDC:66184-401-01	30 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/01/2013	

Labeler - Coty US LLC (789573201)**Registrant** - Coty Inc. (958662223)**Establishment**

Name	Address	ID/FEI	Business Operations
Lancaster		40 10 11325	manufacture(66 184-40 1)

Revised: 12/2013

Coty US LLC