

**CK ONE 3-IN-1 FACE MAKEUP WITH SPF 8 SUNSCREEN 350 WARM SAND- 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.*

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**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, heptanyl diethylhexanoate, butylene glycol, hydroxyethyl acrylate, polyacrylamide, mica, glycerin, vinyl dimethacrylate/methylacrylate copolymer, poly-10 dimethicone,

**Drug Facts (continued)**

caprylic/capric triglyceride, distardimonium hectorite, phenoxymethanol methylmethacrylate copolymer, caprylyl glycol, dimethicone dimethylsiloxane, perfume/fragrance, retinyl palmitate, sodium hydroxide, tocopheryl acetate, zinc oxide, ascorbic acid, silica, acetylsalicylic acid, benzophenone, butyl methoxydibenzoylmethane, 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
- melts 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 Avenue • 20007 Falls  
Chase, MD, USA



350  
warm sand



**CK ONE 3-IN-1 FACE MAKEUP WITH SPF 8 SUNSCREEN 350 WARM SAND**

titanium dioxide and octinoxate liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66184-402
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>Water</b> (UNII: 059QF0KO0R)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THF5PC10R)	
<b>Neopentyl Glycol</b> (UNII: QI80HXD6S5)	
<b>Butylene Glycol</b> (UNII: 3XUS85K0RA)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>Tricaprin</b> (UNII: O1PB8EU98M)	
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>Methyl Methacrylate</b> (UNII: 196OC77688)	
<b>Caprylyl Glycol</b> (UNII: 00YIU5438U)	
<b>Aluminum Dimyristate</b> (UNII: J2KA067N9O)	
<b>Triethoxycaprylylsilane</b> (UNII: LDC331P08E)	
<b>Vitamin A Palmitate</b> (UNII: 1D1K0N0VVC)	
<b>Hyaluronate Sodium</b> (UNII: YSE9PPT4TH)	
<b>Alpha-Tocopherol Acetate</b> (UNII: 9E8X80D2L0)	
<b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>Disodium Stearoyl Glutamate</b> (UNII: 45ASM2L11M)	
<b>Sorbic Acid</b> (UNII: X045WJ989B)	
<b>Alaria Esculenta</b> (UNII: EJ9JK8J58D)	
<b>Tocopherol</b> (UNII: R0ZB2556P8)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:66184-402-02	1 in 1 BOX		
1	NDC:66184-402-01	30 mL in 1 BOTTLE		

**Marketing Information**

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

**Registrant** - Coty Inc. (958662223)

**Establishment**

Name	Address	ID/FEI	Business Operations
Lancaster		40 10 11325	manufacture(66 184-402)

Revised: 12/2013

Coty US LLC