

CK ONE 3-IN-1 FACE MAKEUP WITH SPF 8 SUNSCREEN 850 TOFFEE- 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

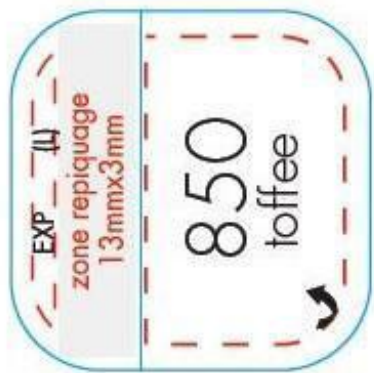
aqua/water/eau, cyclopentasiloxane, neopentyl glycol diethylhexanoate, butylene glycol, hdi/trimethylol crosspolymer, mica, glycerin, vinyl dimethicone/methicone silsesquioxane crosspolymer, peg-10 dimethicone, caprylic/capric triglyceride, disteardimonium hectorite, phenoxyethanol, methyl methacrylate 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	Proprietary blend: Caffeine 25 mg Theobromine 25 mg L-lysine 25 mg
Warnings	Other information
Directions	Quantity of contents
Other information	Other information

ck
Café

Calvin Klein
The One

850
toffee



CK ONE 3-IN-1 FACE MAKEUP WITH SPF 8 SUNSCREEN 850 TOFFEE

titanium dioxide and octinoxate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66184-436
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: 0THT5PC10R)	
Neopentyl Glycol (UNII: Q180HXD6S5)	
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:66184-436-02	1 in 1 BOX		
1	NDC:66184-436-01	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		401011325	manufacture(66184-436)

Revised: 3/2013

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