

CK ONE WATERFRESH FACE MAKEUP SPF 15 450 GOLDEN- titanium dioxide cream
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 2.5%

Titanium dioxide 5.0%

Sunscreen

Keep out of reach 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, **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.

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

aqua/water/eau, hydrogenated polyisobutene, isohexadecane, dextrin palmitate, butylene glycol, hydrogenated lecithin, alcohol, triethylhexanoin, quaternium-90, bentonite, pentylene glycol, glycerin, peg-15/lauryl dimethicone crosspolymer, stearyl inulin, phenoxyethanol, isopropyl titanium triisostearate, octyldodecyl pca, lysine, isododecane, dipropylene glycol, magnesium chloride, sodium chloride, sodium citrate, may contain: iron oxides, titanium dioxide, mica.

ck
one

Calvin Klein

ck one water fresh face makeup SPF 15



200% FPO





CK ONE WATERFRESH FACE MAKEUP SPF 15 450 GOLDEN

titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66184-465
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	4.95 mL in 9.9 g
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	2.4 mL in 9.9 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Isohexadecane (UNII: 918X10UF1E)	

Butylene Glycol (UNII: 3XUS85K0RA)
Hydrogenated Soybean Lecithin (UNII: H1109Z9J4N)
Alcohol (UNII: 3K9958V90M)
Triethylhexanoin (UNII: 7K3W1BIU6K)
Pentylene Glycol (UNII: 50C1307PZG)
Glycerin (UNII: PDC6A3C0OX)
Lysine (UNII: K3Z4F929H6)
Isododecane (UNII: A8289P68Y2)
Dipropylene Glycol (UNII: E107L85C40)
Magnesium Chloride (UNII: 02F3473H9O)
Sodium Chloride (UNII: 451W47IQ8X)
Potassium Chloride (UNII: 660YQ98I10)
Sodium Citrate (UNII: 1Q73Q2JULR)
Mica (UNII: V8A1AW0880)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66184-465-01	9.9 g in 1 CARTRIDGE		
2	NDC:66184-465-02	9.9 g in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/23/2012	

Labeler - Coty US LLC (789573201)

Registrant - Coty Inc. (958662223)

Establishment

Name	Address	ID/FEI	Business Operations
Intercos Europe S.p.A.		438961310	manufacture