

CK ONE AIRLIGHT PRESSED POWDER SPF 15 TAN 500- titanium dioxide powder
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.

Active Ingredients

Titanium Dioxide 14.75%

Zinc Oxide 1%

Talc, Dimethicone, Polymethylsilsequioxane, Dimethicone/Vinyl Dimethicone Crosspolymer, Zinc Stearate, Silica, Phenyl Trimthicone, Synthetic Fluorphlogopite, Caprylyl Methicone, Caprylyl Glycol, Methicone, Zea Mays (Corn) sTarch, Phenoxyethanol, Hyxylene Glycol, [May contain: Iron Oxides, Mica]

ck
one

Calvin Klein

ck one airlight pressed powder SPF 15



200% FPO





CK ONE AIRLIGHT PRESSED POWDER SPF 15 TAN 500

titanium dioxide powder

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:66184-510 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|------------------|
| Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP) | Titanium Dioxide | 1.475 mg in 10 g |
| Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z) | Zinc Oxide | 100 mg in 10 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| Talc (UNII: 7SEV7J4R1U) | |
| Dimethicone (UNII: 92RU3N3Y1O) | |
| Zinc Stearate (UNII: H92E6QA4FV) | |
| Silicon Dioxide (UNII: ETJ7Z6XBU4) | |
| Phenyl Trimethicone (UNII: DR0K5NOJ4R) | |
| Starch, corn (UNII: O8232NY3SJ) | |
| Phenoxyethanol (UNII: HIE492ZZ3T) | |
| Hexylene Glycol (UNII: KEH0A3F75J) | |
| Mica (UNII: V8A1AW0880) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-------------------|---------------------|----------------------|--------------------|
| 1 | NDC:66 184-510-01 | 10 g in 1 CARTRIDGE | | |
| 2 | NDC:66 184-510-02 | 10 g in 1 BOX | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 01/24/2012 | |

Labeler - Coty US LLC (789573201)

Registrant - Coty Inc. (958662223)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|------------------------|
| Intercos Europe S.p.A. | | 438961310 | manufacture(66184-510) |

Revised: 11/2013

Coty US LLC