

ALMOST POWDER COMPACT MAKEUP SPF 15- titanium dioxide powder
CLINIQUE LABORATORIES INC

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 INGREDIENT: TITANIUM DIXOIDE, 6.9%

INACTIVE INGREDIENTS: talc [] silica [] isostearyl palmitate [] methicone [] sodium hyaluronate [] triethoxycaprylylsilane [] nylon-12 [] glycerin [] tocopheryl acetate [] alumina [] tetrasodium edta [] chlorphenesin [] potassium sorbate [] sodium dehydroacetate [] [+/- mica [] titanium dioxide (ci 77891) [] iron oxides (ci 77491, ci 77492, ci 77499)]

WARNING: KEEP OUT OF EYES. STOP USE IF IRRITATION OCCURS. KEEP OUT OF REACH OF CHILDREN.

PRINCIPAL DISPLAY PANEL:

CLINIQUE

ALMOST POWDER

COMPACT MAKEUP

SPF 15

NT WT ..35 OZ / 10 g

CLINIQUE LABORATORIES, DIST

NY, NY 10022



ALMOST POWDER COMPACT MAKEUP SPF 15

titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-724
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	6.9 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
TALC (UNII: 7SEV7J4R1U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TRIETHOXYCAPRYL YLSILANE (UNII: LDC331P08E)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALUMINUM OXIDE (UNII: LM26O6933)	
EDETATE SODIUM (UNII: MP1J8420LU)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM DEHYDRO ACETATE (UNII: 8W46YN971G)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-724-01	1 in 1 CARTON		
1	NDC:49527-724-02	10 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/01/2009	

Labeler - CLINIQUE LABORATORIES INC (173047747)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		205952385	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Len-Ron Manufacturing Division of Aramis Inc.		809771152	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Aramis Inc.		042918826	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Northtec Bristol		949264774	manufacture, relabel, repack

Establishment

Name	Address	ID/FEI	Business Operations
Northtec Keystone		618107429	manufacture, relabel, repack

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2		828534516	manufacture, relabel, repack

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics, Ltd.		255175580	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics, Ltd		253616536	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics Distribution Center		208579636	repack, relabel

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Kabushiki Kaisha		712808195	relabel, repack

Establishment

Name	Address	ID/FEI	Business Operations
Whitman Laboratories Ltd.		216866277	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	manufacture