

**SUPERBALANCED MAKEUP SPF 15 MINERAL RICH FORMULA- 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 dioxide 6.30%

inactive ingredients: talc [] mica [] octyldodecyl stearoyl stearate [] zinc stearate [] zinc laurate [] dimethicone [] bentonite [] hdi/trimethylol hexyllactone crosspolymer [] silica [] hydrolyzed soy protein [] glycerin [] lauroyl lysine [] astrocaryum murumuru seed butter [] squalane [] cetearyl dimethicone crosspolymer [] lecithin [] triethoxycaprylylsilane [] tocopheryl acetate [] tetrahexyldecyl ascorbate [] magnesium myristate [] coconut acid [] water\aquaeau [] tetrasodium edta [] chlorphenesin [] potassium sorbate [] [+/- titanium dioxide (ci 77891) [] iron oxides (ci 77491, ci 77492, ci 77499) [] bismuth oxychloride (ci 77163)

warning: keep out of eyes. stop use if irritation occurs. keep out of reach of children.

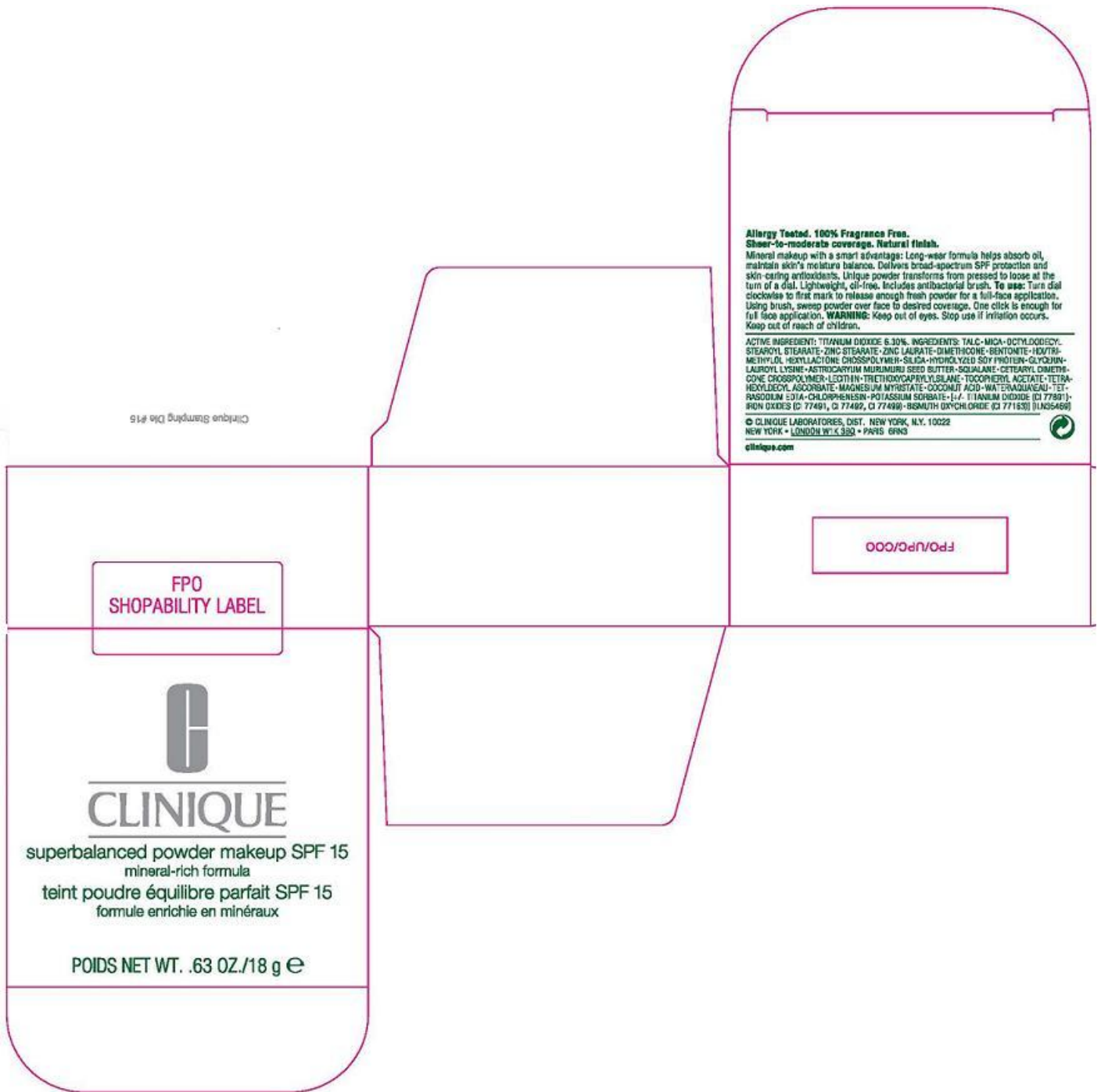
clinique

superbalanced powder makeup
spf 15

mineral-rich formula

net wt. 0.63 oz/ 18g

clinique laboratories distr.
new york, ny 10022



SUPERBALANCED MAKEUP SPF 15 MINERAL RICH FORMULA

titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-746
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	6.3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
TALC (UNII: 7SEV7J4R1U)	
MICA (UNII: V8A1AW0880)	
OCTYLDODECYL STEAROYL STEARATE (UNII: 3D47Q6D93C)	
ZINC STEARATE (UNII: H92E6QA4FV)	
ZINC LAURATE (UNII: 4YOP58Y695)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BENTONITE (UNII: A3N5ZCN45C)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAUROYL LYSINE (UNII: 113171Q70B)	
ASTROCARYUM MURUMURU SEED BUTTER (UNII: 12V64UPU6R)	
SQUALANE (UNII: GW89575KF9)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
MAGNESIUM MYRISTATE (UNII: Z1917F0578)	
COCONUT ACID (UNII: 40U37V505D)	
WATER (UNII: 059QF0K00R)	
EDETATE SODIUM (UNII: MP1J8420LU)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-746-01	1 in 1 CARTON		
1	NDC:49527-746-02	18 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/01/2010	

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

