DOUBLE WEAR MINERAL RICH LOOSE POWDER MAKEUP SPF 12- titanium dioxide powder ESTEE LAUDER 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 2.2%

INACTIVE INGREDIENTS: TALC [] ZINC STEARATE [] CAPRYLYL METHICONE [] OCTYLDODECYL STEAROYL STEARATE [] BIS-HYDROXYETHOXYPROPYL DIMETHICONE/IPDI COPOLYMER ETHYLCARBAMTE [] CAPRYLYL GLYCOL [] HEXYLENE GLYCOL [] DEHYDROACETIC ACID [] [+/- MICA [] IRON OXIDES (CI 77491, CI 77492, CI 77499) [] ZINC OXIDE (CI 77947) [] TITANIUM DIOXIDE (CI 77891) [] YELLOW 5 LAKE (CI 19140) [] CHROMIUM OXIDE GREENS (CI 77288) [] CHROMIUM HYDROXIDE GREEN (CI 77289) [] FERRIC FERROCYANIDE (CI 77510) [] CARMINE (CI 75470) [] BISMUTH OXYCHLORIDE (CI 77163) [] BLUE 1 LAKE (CI 42090)]

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

PRINCIPAL DISPLAY PANEL:

ESTEE LAUDER

DOUBLE WEAR

MINERAL RICH LOOSE POWDER MAKEUP

SPF 12

NT WT 0.39 OZ/11 g

ESTEE LAUDER DIST NEW YORK, NY 10022



DOUBLE WEAR MINERAL RICH LOOSE POWDER MAKEUP SPF 12

titanium dioxide powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11559-014

Route of Administration TOPICAL

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	2.2 g in 100 g			

Inactive Ingredients	
Ingredient Name	Strength
TALC (UNII: 7SEV7J4R1U)	
ZINC STEARATE (UNII: H92E6QA4FV)	
OCTYLDODECYL STEAROYL STEARATE (UNII: 3D47Q6D93C)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
HEXYLENE GLYCOL (UNII: KEH0 A3F75J)	
DEHYDRO ACETIC ACID (UNII: 2KAG279R6R)	
MICA (UNII: V8 A1AW0 880)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
CHROMIC OXIDE (UNII: X5Z09SU859)	
CO CHINEAL (UNII: TZ8Z31B35M)	
FERRIC FERRO CYANIDE (UNII: TLE294X33A)	
BISMUTH O XYCHLO RIDE (UNII: 4ZR792I587)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:11559-014-01	1 in 1 CARTON		
1 NDC:11559-014-02	11 g in 1 JAR		

Marketing Inform	mation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2010	

Labeler - ESTEE LAUDER INC (005914387)

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.		0 429 18 8 26	manufacture

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

Establishment			
Name	Address	ID/FEI	Business Operations
Northtec Keystone		6 18 10 7429	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
INTERCOS		071352058	manufacture

Revised: 11/2011 ESTEE LAUDER INC