

**THE TREATMENT POWDER FOUNDATION SPF 15- titanium dioxide, octinoxate powder  
MAX HUBER RESEARCH LAB 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 INGREDIENTS: TITANIUM DIOXIDE, 4.9% [] OCTINOXATE 4.5%

INACTIVE INGREDIENTS: TALC [] DIMETHICONE [] SILICA [] BORON NITRIDE []  
OCTYLDODECYL STEAROYL STEARATE [] NYLON-12 [] POLYMETHYL METHACRYLATE []  
YEAST EXTRACT\FAEX\EXTRAIT DE LEVURE [] POLYGLYCERYL-3 DIISOSTEARATE []  
POLYPERFLUOROMETHYLISOPROPYL ETHER [] METHICONE [] MALACHITE []  
TOURMALINE [] ZEOLITE [] CAPRYLYL GLYCOL [] ORYZANOL [] TOCOPHERYL ACETATE  
[] CALCIUM CARBONATE [] PENTAERYTHRITYL TETRA-DI-T-BUTYL  
HYDROXYHYDROCINNAMATE [] HEXYLENE GLYCOL [] PHENOXYETHANOL [] SORBIC  
ACID [] [+/- MICA [] BISMUTH OXYCHLORIDE (CI 77163) [] TITANIUM DIOXIDE (CI 77891) []  
ZINC OXIDE (CI 77947) [] 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:

skin color de la mer

LA MER

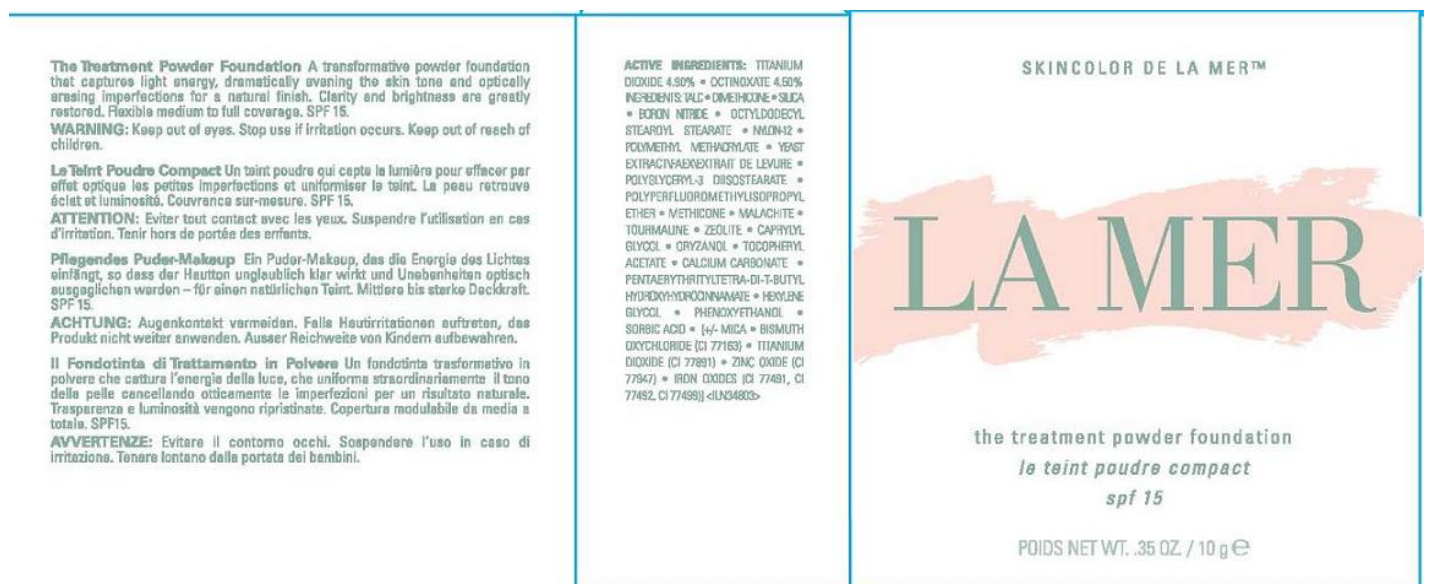
the treatment powder foundation

spf 15

net wt. 0.35 oz./10 g

MAX HUBER RESEARCH LABS INC DISTR.

NEW YORK, NY 10022



# THE TREATMENT POWDER FOUNDATION SPF 15

titanium dioxide, octinoxate powder

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65966-111
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4.9 g in 100 g
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4.5 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>BORON NITRIDE</b> (UNII: 2U4T60A6YD)	
<b>OCTYLDODECYL STEAROYL STEARATE</b> (UNII: 3D47Q6D93C)	
<b>YEAST</b> (UNII: 3NY3SM6B8U)	
<b>CUPRIC CARBONATE</b> (UNII: 9AOA5F11GJ)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>GAMMA ORYZANOL</b> (UNII: SST9XCL51M)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE)</b> (UNII: 255PIF62MS)	
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>BISMUTH OXYCHLORIDE</b> (UNII: 4ZR792I587)	
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65966-111-01	1 in 1 CARTON		
1	NDC:65966-111-02	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	01/01/2008	

**Labeler** - MAX HUBER RESEARCH LAB INC (926708694)

## 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**

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

**Establishment**

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

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Aveda Corporation		071352058	manufacture

Revised: 7/2011

MAX HUBER RESEARCHLAB INC