

**ALMOST POWDER MAKEUP SPF 15- titanium dioxide, octinoxate 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.*

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active ingredients: titanium dioxide 13.00% [] octinoxate 2.00%

inactive ingredients: talc [] dimethicone [] nylon-12 [] silica [] squalane [] boron nitride [] vinyl dimethicone/methicone silsesquioxane crosspolymer [] cetyl caprylate [] diisostearyl malate [] phytosteryl/isostearyl/cetyl/stearyl/behenyl dimer dilinoleate [] methicone [] aluminum hydroxide [] glycerin [] sodium hyaluronate [] magnesium palmitoyl glutamate [] sodium palmitoyl sarcosinate [] palmitoyl proline [] alumina [] tocopherol [] palmitic acid [] 1,2-hexanediol [] ascorbyl tetraisopalmitate [] tin oxide [] sodium dehydroacetate [] [+/- iron oxides (ci 77499, ci 77492, ci 77491) [] mica [] titanium dioxide (ci 77891)]

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

principal display panel:

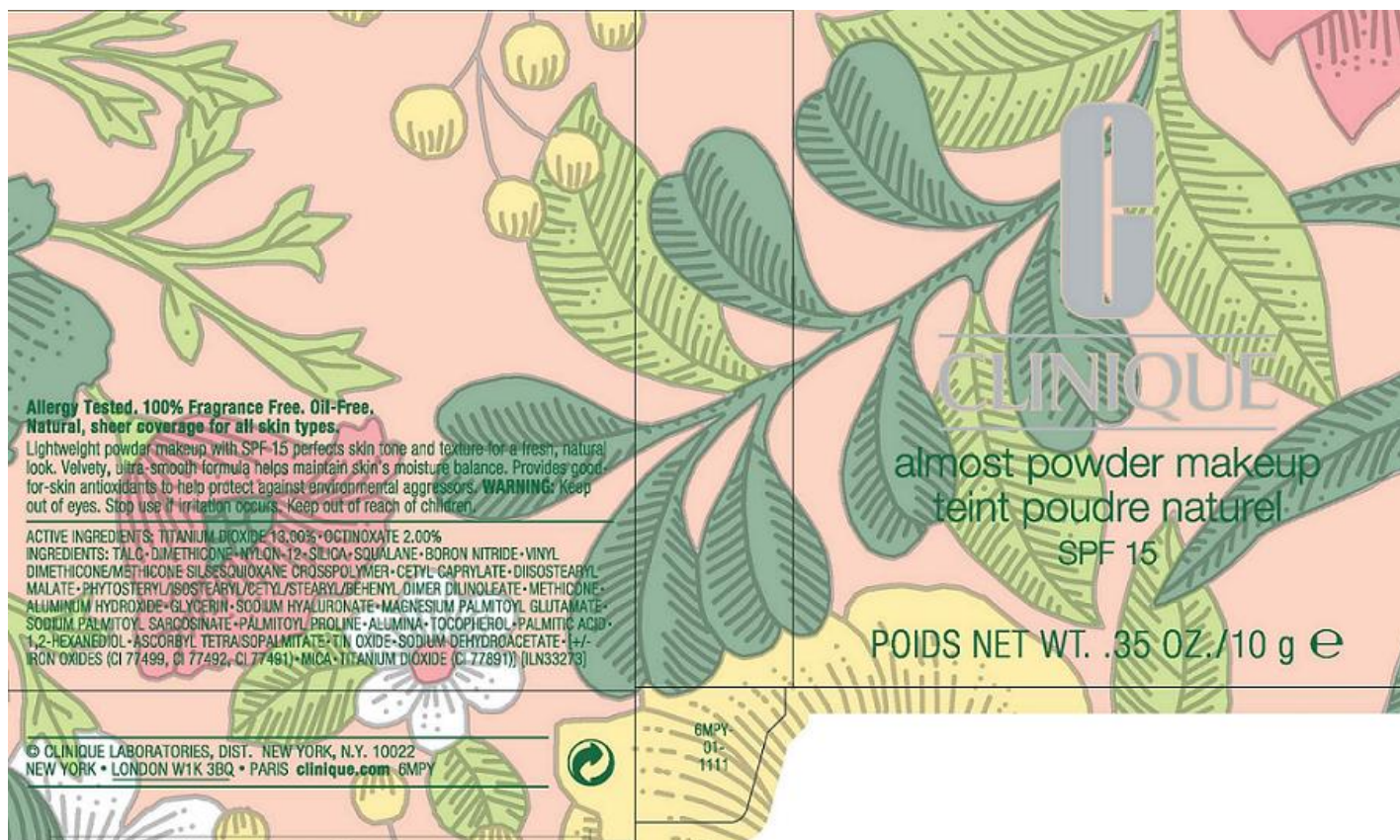
CLINIQUE

ALMOST POWDER MAKEUP

SPF 15

NT WT. 0.35 OZ/ 10 g

clinique laboratories dist.  
new york, ny 10022



## ALMOST POWDER MAKEUP SPF 15

titanium dioxide, octinoxate powder

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49527-800
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	13.0 g in 100 g
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.0 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>TALC</b> (UNII: 7SEV7J4RIU)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SQUALANE</b> (UNII: GW89575KF9)	

BORON NITRIDE (UNII: 2U4T60A6YD)
CETYL OCTANOATE (UNII: 418Q5V6PLJ)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
GLYCERIN (UNII: PDC6A3C0OX)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
SODIUM PALMITOYL GLUTAMATE (UNII: KVF4175O54)
ALUMINUM OXIDE (UNII: LM26O6933)
TOCOPHEROL (UNII: R0ZB2556P8)
PALMITIC ACID (UNII: 2V16EO95H1)
HEXANEDIOL (UNII: ZIA319275I)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
TIN (UNII: 387GMG9FH5)
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:49527-800-01	1 in 1 CELLO PACK		
1	NDC:49527-800-02	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	06/01/2007	

**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		6 18 10 7429	manufacture, relabel, repack

### Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2		8 28 534516	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

### Establishment

Name	Address	ID/FEI	Business Operations
ASANUMA CORP LTD		700717762	manufacture