

**ALMOST BRONZER 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.

**CLINIQUE
almost bronzer
SPF 15**

WARNING

Keep out of eyes.

Stop use if irritation occurs.

Keep out of reach of children.

ACTIVE INGREDIENT

TITANIUM DIOXIDE 9.80%

INGREDIENTS

TALC • ZINC STEARATE • ISOSTEARYL PALMITATE • SILICA • METHICONE •
TRIETHOXYCAPRYLYLSILANE • LECITHIN • TOCOPHERYL ACETATE • GLYCERIN •
SODIUM HYALURONATE • NYLON-12 • ALUMINA • TIN OXIDE • TETRASODIUM EDTA •
SODIUM DEHYDROACETATE • CHLORPHENESIN • POTASSIUM SORBATE • [+/- MICA •
IRON OXIDES (CI 77491 • CI 77492 • CI 77499) • BISMUTH OXYCHLORIDE (CI 77163) •
TITANIUM DIOXIDE (CI 77891) • RED 7 LAKE (CI 15850) • YELLOW 5 LAKE (CI 19140) • BLUE
1 LAKE (CI 42090) • CARMINE (CI 75470)] [ILN34967]

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PRINCIPAL DISPLAY PANEL - 9g Carton

**C
CLINIQUE**

almost bronzer

SPF 15

poudre bronzante

teint naturel

POIDS NET WT. .31 OZ./9 g e



ALMOST BRONZER SPF 15

titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-801
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	9.8 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
talc (UNII: 7SEV7J4R1U)	
zinc stearate (UNII: H92E6QA4FV)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
triethoxycaprylylsilane (UNII: LDC331P08E)	

glycerin (UNII: PDC6A3C0OX)
hyaluronate sodium (UNII: YSE9PPT4TH)
stannic oxide (UNII: KM7N50LOS6)
edetate sodium (UNII: MP1J8420LU)
sodium dehydroacetate (UNII: 8W46YN971G)
chlorphenesin (UNII: I670DAL4SZ)
potassium sorbate (UNII: 1VPU26JZZ4)
ferric oxide red (UNII: 1K09F3G675)
ferric oxide yellow (UNII: EX438O2MRT)
ferrosoferric oxide (UNII: XM0M87F357)
bismuth oxychloride (UNII: 4ZR792I587)
cochineal (UNII: TZ8Z31B35M)
D&C red no. 7 (UNII: ECW0LZ41X8)
FD&C yellow no. 5 (UNII: I753WB2F1M)
FD&C blue no. 1 (UNII: H3R47K3TBD)
aluminum oxide (UNII: LM26O6933)
lecithin, soybean (UNII: 1DI56QDM62)
mica (UNII: V8A1AW0880)
alpha-tocopherol acetate (UNII: 9E8X80D2L0)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-801-01	1 in 1 CARTON		
1		9 g in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	09/01/2001	

Labeler - clinique laboratories inc (173047747)

Establishment

Name	Address	ID/FEI	Business Operations
ELGC Kabushiki Kaisha		712808195	RELABEL, REPACK

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2 (PADC 2)		828534516	MANUFACTURE, RELABEL, REPACK

Establishment

Name	Address	ID/FEI	Business Operations
ARAMIS, INC		042918826	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 COSMETICS, LTD		253616536	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE

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
NORTEC KEYSTONE		787336577	MANUFACTURE, RELABEL, REPACK

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
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE