

**CONTINUOUS COVERAGE MAKEUP BROAD SPECTRUM SPF 15- titanium dioxide cream
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.

CONTINUOUS COVERAGE MAKEUP BROAD SPECTRUM SPF 15

Drug Facts

Active ingredient

Titanium Dioxide 2.1%

Purpose

Sunscreen

Use

helps prevent sunburn

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every two hours
- use a water resistant sunscreen if swimming or sweating
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. – 2 p.m.
 - wear long-sleeved shirts, pants, hats and sunglasses
- children under 6 months of age: ask a doctor

Inactive ingredients

water/aqua/eau • hydrogenated polydecene • talc • butylene glycol • isostearic acid • glyceryl stearate • peg-100 stearate • phenyl trimethicone • magnesium aluminum silicate • tromethamine • cholesterol • alginate • microcrystalline cellulose • cellulose gum • disteardimonium hectorite • sodium hyaluronate • triethyl citrate • lecithin • stearic acid • aluminum hydroxide • phenoxyethanol • [+/- mica • titanium

dioxide (ci 77891) • iron oxides (ci 77491) • iron oxides (ci 77492) • iron oxides (ci 77499) • bismuth oxychloride (ci 77163)] [iln43112]

Other information

protect the product in this container from excessive heat and direct sun

PRINCIPAL DISPLAY PANEL - 30 ml Tube Carton

CLINIQUE

continuous

coverage

makeup

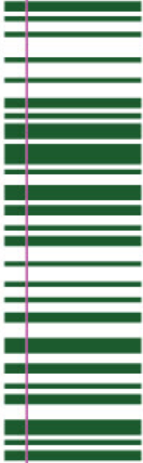
broad spectrum

SPF 15

POIDS NET WT.

1 OZ./30 ml e

C1636603



COO-UPC/FPO

647G-01-111F

Drug Facts (continued)

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Drug Facts (continued)

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Drug Facts (continued)

Other information

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Allergy Tested. 100% Fragrance Free. Full cover. Natural matte finish.
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continuous
coverage
makeup
broad spectrum
SPF 15

POIDS NET WT.
1 OZ./30 ml e

FPO
SHOPABILITY
LABEL

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CONTINUOUS COVERAGE MAKEUP BROAD SPECTRUM SPF 15

titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-071
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.0273 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
TALC (UNII: 7SEV7J4R1U)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
TROMETHAMINE (UNII: 023C2WHX2V)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-071-01	1 in 1 CARTON	01/01/2011	
1		30 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2011	

Labeler - CLINIQUE LABORATORIES INC. (173047747)**Establishment**

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(49527-071) , REPACK(49527-071)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(49527-071)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(49527-071)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(49527-071)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(49527-071)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(49527-071) , REPACK(49527-071)

Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(49527-071) , REPACK(49527-071)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(49527-071)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(49527-071)

Revised: 1/2019

CLINIQUE LABORATORIES INC.