

**CONTINUOUS COVERAGE MAKEUP 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.

DRUG FACTS

ACTIVE INGREDIENT: 2% TITANIUM DIOXIDE

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 2 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 AM TO 2 PM
 - ◦ WEAR LONG-SLEEVED SHIRTS, PANTS AND SUNGLASSES
 - ◦ CHILDREN UNDER 6 MONTHS OF AGE: ASK A DOCTOR

INACTIVE INGREDIENTS: water\aquaeau [] polydecene [] talc [] butylene glycol [] isostearic acid [] glyceryl stearate [] peg-100 stearate [] phenyl trimethicone [] magnesium aluminum silicate [] tromethamine [] cholesterol [] algin [] microcrystalline cellulose [] cellulose gum [] disteardimonium hectorite [] sodium hyaluronate [] triethyl citrate [] lecithin [] stearic acid [] aluminum hydroxide [] polyaminopropyl biguanide [] phenoxyethanol [] [+/- mica [] titanium dioxide (ci 77891) [] iron oxides (ci 77491, ci 77492, ci 77499) [] bismuth oxychloride (ci 77163)

PROTECT THE PRODUCT IN THIS CONTAINER FROM EXCESSIVE HEAT AND DIRECT SUN
PRINCIPAL DISPLAY PANEL

CLINIQUE

CONTINUOUS
 COVERAGE
 MAKEUP
 BROAD SPECTRUM
 SPF 15
 NET WT. 1 OZ/ 30 ML

CLINIQUE LABORATORIES DIST
 NY NY 10022

Drug Facts (continued)

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:

Drug Facts (continued)

- 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 • polydecene • talc • butylene glycol • isostearic acid • glyceryl stearate • peg-100 stearate • phenyl trimethicone • magnesium aluminum silicate • tromethamine • cholesterol • algin • microcrystalline cellulose • cellulose gum • disteardimonium hectorite • sodium hyaluronate

Drug Facts (continued)

triethyl citrate • lecithin • stearic acid • aluminum hydroxide • polyaminopropyl biguanide • phenoxyethanol • [+/- mica • titanium dioxide (ci 77891) • iron oxides (ci 77491, ci 77492, ci 77499) • bismuth oxychloride (ci 77163)] [In37316]

Drug Facts (continued)

Other Information

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

Allergy Tested. 100% Fragrance Free. Full cover. Natural matte finish.

© CLINIQUE LABORATORIES, DIST. NEW YORK, N.Y. 10022 NEW YORK • LONDON W1K 3BQ • PARIS clinique.com 6476



POIDS NET WT.
 1 OZ./30 ml e

broad spectrum
 SPF 15
 coverage
 makeup
 continuous

CLINIQUE

Drug Facts

Active ingredient

Titanium Dioxide 2.0%

Purpose

Sunscreen

Use helps prevent sunburn

Warnings

For external use only

Drug Facts (continued)

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.

CONTINUOUS COVERAGE MAKEUP SPF 15

titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.0 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
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)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
POLYAMINOPROPYL BIGUANIDE (UNII: 322U039GMF)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MICA (UNII: V8A1AW0880)	
IRON (UNII: E1UOL152H7)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-010-01	1 in 1 CARTON		
1	NDC:49527-010-02	30 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/1992	

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		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

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

Revised: 12/2011

CLINIQUE LABORATORIES INC