CLINIQUE SPF 50 BROAD SPECTRUM MINERAL SUNSCREEN FLUID FOR FACE-titanium dioxide and zinc oxide lotion
CLINIQUE LABORATORIES LLC

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 SPF 50 BROAD SPECTRUM MINERAL SUNSCREEN FLUID FOR FACE

Drug Facts

Active ingredients

Titanium Dioxide 6.3%

Zinc Oxide 4.0%

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•dimethicone•butyloctyl salicylate•polydiethylsiloxane•c12-15 alkyl benzoate•isononyl isononanoate•diethylhexyl succinate•neopentyl glycol diheptanoate•methyl trimethicone•butylene glycol•ethylhexyl methoxycrylene•lauryl peg-9 polydimethylsiloxyethyl dimethicone•silica•dipentaerythrityl tri-polyhydroxystearate•laureth-4•cetyl peg/ppg-10/1 dimethicone•dimethicone/peg-10/15 crosspolymer•dimethicone silylate•hydrolyzed wheat protein/pvp crosspolymer•triethoxycaprylylsilane•dimethicone crosspolymer-3•isostearic acid•caprylyl glycol•polyhydroxystearic acid•dipropylene glycol•phenoxyethanol•iron oxides (ci 77492)•iron oxides (ci 77491) [iln41953]

Other information

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

PRINCIPAL DISPLAY PANEL - 30 ml Bottle Carton

CLINIQUE

broad
spectrum
SPF 50

UVA
UVB
invisible shield
technology

mineral
sunscreen fluid
for face

sensitive skin formula

1 FL.OZ.
30 ml e

CLINIQUE SPF 50 BROAD SPECTRUM MINERAL SUNSCREEN FLUID FOR FACE

titanium dioxide and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49527-752
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	63 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
DIETHYLHEXYL SUCCINATE (UNII: 69W9UMG3P8)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
METHYL TRIMETHICONE (UNII: S73ZQI0GXM)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIPENTAERYTHRITYL TRI-POLYHYDROXYSTEARATE (UNII: D21K655H52)	
LAURETH-4 (UNII: 6HQ855798J)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-752-01	1 in 1 CARTON	06/01/2016	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	06/01/2016	

Labeler - CLINIQUE LABORATORIES LLC (044475127)

Registrant - Estee Lauder Companies Inc. (790802086)

Establishment

Name	Address	ID/FEI	Business Operations
PALC		078364654	pack(49527-752) , label(49527-752)

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics Ltd.		204132062	pack(49527-752) , label(49527-752)

Establishment

Name	Address	ID/FEI	Business Operations
Whitman Laboratories Ltd.		216866277	manufacture(49527-752) , pack(49527-752) , label(49527-752)

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder N.V.		370151326	manufacture(49527-752) , pack(49527-752) , label(49527-752)

Establishment

Name	Address	ID/FEI	Business Operations
The Estee Lauder Inc		802599436	manufacture(49527-752) , pack(49527-752) , label(49527-752)

Establishment

Name	Address	ID/FEI	Business Operations
Northtec LLC		943871157	pack(49527-752) , label(49527-752)

Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	pack(49527-752) , label(49527-752)