

EVEN BETTER MAKEUP BROAD SPECTRUM SPF 15- octinoxate, titanium dioxide, and zinc oxide liquid

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.

**EVEN BETTER MAKEUP
BROAD SPECTRUM SPF 15**

Drug Facts

Active ingredients

Octinoxate 5.9%

Titanium Dioxide 3.5%

Zinc Oxide 2.8%

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\aquaeau • methyl trimethicone • phenyl trimethicone • dimethicone • triethylhexanoin • butylene glycol • trimethylsiloxysilicate • yeast extract\faex\extrait de levure • peg-10 dimethicone • lauryl peg-9 polydimethylsiloxylethyl dimethicone • alumina • citrus grandis (grapefruit) peel extract • betula alba (birch) bark extract • saccharomyces lysate extract • astrocaryum murumuru seed butter • c12-15 alkyl benzoate • glycerin • sodium myristoyl sarcosinate • acetyl glucosamine • caprylyl methicone • methicone • polyglyceryl-6 polyricinoleate • disteardimonium hectorite • dimethicone crosspolymer-3 • isopropyl titanium triisostearate • lecithin • laureth-7 • tocopheryl acetate • magnesium ascorbyl phosphate • dimethicone/peg-10/15 crosspolymer • dipropylene glycol • sodium chloride • caprylyl glycol • tetrahexyldecyl ascorbate • disodium edta • phenoxyethanol • polyaminopropyl biguanide • [+/- titanium dioxide (ci 77891) • iron oxides (ci 77491, ci 77492, ci 77499) • mica • bismuth oxychloride (ci 77163)] [iln39834]

Other information

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

DIST.

NEW YORK, N.Y. 10022

PRINCIPAL DISPLAY PANEL - 30 ml Bottle Carton

C

CLINIQUE

even better

makeup

broad spectrum

SPF 15

evens and corrects

1 FL.OZ.LIQ./30 ml e



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Drug Facts (continued)

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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:

Inactive ingredients

water/aqua/EAU-methyl trimethicone-phenyl trimethicone-
dimethicone-triethyl xanolan-butylene glycol-
methylsiloxysulfonate-yeast extract/ae extract de levure-
peg-10 dimethicone-lanolin peg-9 polydimethylsiloxethyl
dimethicone-alumina-citrus grandis (grapefruit) peel extract-
beta-alta (birch) bark extract-saccharomyces yeast extract-
astrocaryum murumuru seed butter-c12-15 alkyl benzoate-
glycerin-sodium myristyl sarcosinate-acetyl glucosamine-
polyvinyl methicone-methicone-polyglycol-5

Drug Facts (continued)

polycarbonate, disteardiumhexachloride, dimethicone, crosspolymer-3, isopropyl titanium triscroate, behenyl laurate-7, tocopheryl acetate, magnesium ascorbyl phosphate, dimethicone/peg-10/7.5 crosspolymer, dipropylene glycol, sodium chloride, carboxyl glycol, tetrahexyldecyl ascorbate, disodium edta, phenoxethanol, polydimethylsiloxane, (+/-) titanium dioxide (cf. 77491), iron oxides (cf. 77491, cf. 77492, cf. 77499), mica, bis(4-methyl-6-tert-butyl-2-phenyl-1,3,5-triazine) (cf. 77163) [IN39634].

Drug Facts (continued)

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

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NEW YORK, N.Y. 10022
NEW YORK • LONDON W1K 3BQ • PARIS
6MNY



1 FL.OZ.LIQ./30 ml e

CLINIQUE
even better
makeup
broad spectrum
SPF 15
evens and corrects



Dermatologist Developed.

Dermatologist Developed.
Allergy Tested. 100% Fragrance Free. Shake well.

Drug Facts

Active ingredients

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Titanium Dioxide 3.5%
Zinc Oxide 2.8%

— 100 —

Purpose
Sunscreen

Drug Facts (continued)

Use helps prevent sunburn

Warnings

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FPO/UPC/COO

6MNY-
01-
1118

octinoxate, titanium dioxide, and zinc oxide liquid

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:49527-025

Route of Administration		TOPICAL	
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	0.06962 g in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	0.0412 g in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	0.033 g in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
water (UNII: 059QF0KO0R)			
methyl trimethicone (UNII: S73ZQI0GXM)			
phenyl trimethicone (UNII: DR0K5NOJ4R)			
dimethicone (UNII: 92RU3N3Y1O)			
triethylhexanoin (UNII: 7K3W1BIU6K)			
butylene glycol (UNII: 3XUS85K0RA)			
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)			
aluminum oxide (UNII: LMI26O6933)			
citrus maxima fruit rind (UNII: 5NX3G75CA6)			
betula pubescens bark (UNII: 3R504894L9)			
saccharomyces lysate (UNII: R85W246Z1C)			
astrocaryum murumuru seed butter (UNII: 12V64UPU6R)			
alkyl (c12-15) benzoate (UNII: A9EJ3J61HQ)			
glycerin (UNII: PDC6A3C0OX)			
sodium myristoyl sarcosinate (UNII: J07237209D)			
n-acetylglucosamine (UNII: V956696549)			
caprylyl trisiloxane (UNII: Q95M2P1KJL)			
isopropyl titanium triisostearate (UNII: 949E3KBJ1I)			
laureth-7 (UNII: Z95S6G8201)			
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)			
magnesium ascorbyl phosphate (UNII: 0R822556M5)			
dipropylene glycol (UNII: E107L85C40)			
sodium chloride (UNII: 451W47IQ8X)			
caprylyl glycol (UNII: 00YIU5438U)			
tetrahexyldecyl ascorbate (UNII: 9LBV3F07AZ)			
edetate disodium (UNII: 7FLD91C86K)			
phenoxyethanol (UNII: HIE492ZZ3T)			
POLIHEXANIDE (UNII: 322U039GMF)			
ferric oxide red (UNII: 1K09F3G675)			
ferric oxide yellow (UNII: EX438O2MRT)			
ferrosoferric oxide (UNII: XM0M87F357)			
mica (UNII: V8A1AW0880)			
bismuth oxychloride (UNII: 4ZR792I587)			
Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-025-01	1 in 1 CARTON	09/01/2012	
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 NOT FINAL		part352	09/01/2012	

Labeler - CLINIQUE LABORATORIES LLC (044475127)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(49527-025) , REPACK(49527-025)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(49527-025)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(49527-025)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(49527-025)

Establishment			
Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(49527-025)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(49527-025) , REPACK(49527-025)

Establishment			
Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(49527-025) , REPACK(49527-025)

Establishment			
Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(49527-025)

Establishment			
Name	Address	ID/FEI	Business Operations

ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(49527-025)
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Revised: 11/2019

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