

**EVEN BETTER GLOW LIGHT REFLECTING MAKEUP BROAD SPECTRUM SPF 15-
octinoxate, 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.

EVEN BETTER GLOW LIGHT REFLECTING MAKEUP BROAD SPECTRUM SPF 15

Drug Facts

Active ingredients

Octinoxate 6.0%
Titanium Dioxide 3.8%
Zinc Oxide 3.0%

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\aquaeau • methyl trimethicone • phenyl trimethicone • triethylhexanoin • dimethicone • butylene

glycol • trimethylsiloxysilicate • peg-10 dimethicone • lauryl peg-9 polydimethylsiloxyethyl dimethicone • aluminum hydroxide • c12-15 alkyl benzoate • glycerin • citrus grandis (grapefruit) peel extract • betula alba (birch) bark extract • saccharomyces lysate extract • camellia sinensis leaf extract • astrocaryum murumuru seed butter • yeast extract/faex\extrait de levure • salicylic acid • sodium hyaluronate • caprylyl glycol • jojoba esters • sodium myristoyl sarcosinate • sodium chloride • tocopheryl acetate • acetyl glucosamine • caprylyl methicone • polyglyceryl-6 polyricinoleate • methicone • dimethicone crosspolymer-3 • lecithin • magnesium ascorbyl phosphate • tetrahexyldecyl ascorbate • disteardimonium hectorite • isopropyl titanium triisostearate • laureth-7 • dipropylene glycol • dimethicone/peg-10/15 crosspolymer • disodium edta • phenoxyethanol • [+/- mica • titanium dioxide (ci 77891) • bismuth oxychloride (ci 77163) • iron oxides (ci 77492) • iron oxides (ci 77491) • iron oxides (ci 77499) [iln43351]

Other information

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

PRINCIPAL DISPLAY PANEL - 30 ml Jar Carton

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CLINIQUE

even better glow

light reflecting makeup

broad spectrum

SPF 15

1 FL.OZ.LIQ./30 ml e



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octinoxate, titanium dioxide, and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-056
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.0675 g in 1 mL
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.04275 g in 1 mL

Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.03375 g in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Methyl Trimethicone (UNII: S73ZQI0GXM)	
Phenyl Trimethicone (UNII: DR0K5NOJ4R)	
Triethylhexanoin (UNII: 7K3W1BIU6K)	
Dimethicone (UNII: 92RU3N3Y1O)	
Butylene Glycol (UNII: 3XUS85K0RA)	
PEG-10 Dimethicone (600 CST) (UNII: 8PR7V1SVM0)	
Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone (UNII: 25G622K2RA)	
Aluminum Hydroxide (UNII: 5QB0T2IUN0)	
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
Glycerin (UNII: PDC6A3C0OX)	
Citrus Maxima Fruit Rind (UNII: 5NX3G75CA6)	
Betula Pubescens Bark (UNII: 3R504894L9)	
Saccharomyces Lysate (UNII: R85W246Z1C)	
Green Tea Leaf (UNII: W2ZU1RY8B0)	
Astrocaryum Murumuru Seed Butter (UNII: 12V64UPU6R)	
Yeast, Unspecified (UNII: 3NY3SM6B8U)	
Salicylic Acid (UNII: O414PZ4LPZ)	
Hyaluronate Sodium (UNII: YSE9PPT4TH)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Sodium Myristoyl Sarcosinate (UNII: J07237209D)	
Sodium Chloride (UNII: 451W47IQ8X)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
N-Acetylglucosamine (UNII: V956696549)	
Caprylyl Trisiloxane (UNII: Q95M2P1KJL)	
Methicone (20 CST) (UNII: 6777U11MKT)	
Magnesium Ascorbyl Phosphate (UNII: 0R822556M5)	
Tetrahexyldecyl Ascorbate (UNII: 9LBV3F07AZ)	
Disteardimonium Hectorite (UNII: X687XDK09L)	
Isopropyl Titanium Triisostearate (UNII: 949E3KBJ1I)	
Laureth-7 (UNII: Z95S6G8201)	
Dipropylene Glycol (UNII: E107L85C40)	
Edetate Disodium Anhydrous (UNII: 8NLQ36F6MM)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Mica (UNII: V8A1AW0880)	
Bismuth Oxychloride (UNII: 4ZR792I587)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Ferrosoferric Oxide (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-056-01	1 in 1 CARTON	03/20/2017	

1	30 mL in 1 JAR; 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	03/20/2017	

Labeler - CLINIQUE LABORATORIES LLC (044475127)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(49527-056) , REPACK(49527-056)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(49527-056)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(49527-056)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(49527-056)

Establishment			
Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(49527-056)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(49527-056) , REPACK(49527-056)

Establishment			
Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(49527-056) , REPACK(49527-056)

Establishment			
Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(49527-056)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(49527-056)

