

REDNESS SOLUTIONS MAKEUP BROAD SPECTRUM SPF 15 WITH PROBIOTIC TECHNOLOGY- 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.

REDNESS SOLUTIONS MAKEUP BROAD SPECTRUM SPF 15 WITH PROBIOTIC TECHNOLOGY

Drug Facts

Active ingredients

Octinoxate 5.9%
Titanium Dioxide 3.7%
Zinc Oxide 2.9%

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 • methyl trimethicone • phenyl trimethicone • dimethicone • triethylhexanoin • butylene glycol • trimethylsiloxysilicate • peg-10 dimethicone • lauryl peg-9 polydimethylsiloxylethyl dimethicone • aluminum hydroxide • c12-15 alkyl benzoate • lactobacillus ferment • citrus grandis (grapefruit) peel extract • magnolia grandiflora bark extract • poria cocos sclerotium extract • astrocaryum murumuru seed butter • glycerin • caffeine • sodium myristoyl sarcosinate • caprylyl methicone • methicone • polyglyceryl-6 polyricinoleate • disteardimonium hectorite • acetyl glucosamine • isopropyl titanium triisostearate • dimethicone crosspolymer-3 • lecithin • tocopheryl acetate • laureth-7 • dimethicone/peg-10/15 crosspolymer • sodium chloride • dipropylene glycol • disodium edta • polyaminopropyl biguanide • phenoxyethanol • [+/- mica • titanium dioxide (ci 77891) • iron oxides (ci 77491, ci 77492, ci 77499)] [iln37592]

Other information

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

PRINCIPAL DISPLAY PANEL - 30 ml Bottle Carton

CLINIQUE

redness
solutions

makeup
broad spectrum
SPF 15
with probiotic technology

1 FL.OZ.LIQ./30 ml e



PROBIOTIC TECHNOLOGY

octinoxate, titanium dioxide, and zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-070
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0696 g in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.0437 g in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0342 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)	
peg-10 dimethicone (600 CST) (UNII: 8PR7V1SVM0)	
lauryl peg-9 polydimethylsiloxyethyl dimethicone (UNII: 25G622K2RA)	
aluminum hydroxide (UNII: 5QB0T2IUN0)	
alkyl (c12-15) benzoate (UNII: A9EJ3J61HQ)	
lactobacillus reuteri (UNII: 9913I24QEE)	
grapefruit (UNII: O82C39RR8C)	
astrocaryum murumuru seed butter (UNII: 12V64UPU6R)	
glycerin (UNII: PDC6A3C0OX)	
caffeine (UNII: 3G6A5W338E)	
sodium myristoyl sarcosinate (UNII: J07237209D)	
caprylyl trisiloxane (UNII: Q95M2P1KJL)	
methicone (20 cst) (UNII: 6777U11MKT)	
disteardimonium hectorite (UNII: X687XDK09L)	
n-acetylglucosamine (UNII: V956696549)	
isopropyl titanium triisostearate (UNII: 949E3KBJ1I)	
laureth-7 (UNII: Z95S6G8201)	
sodium chloride (UNII: 451W47IQ8X)	
dipropylene glycol (UNII: E107L85C40)	
edetate disodium anhydrous (UNII: 8NLQ36F6MM)	
phenoxyethanol (UNII: HIE492ZZ3T)	
mica (UNII: V8A1AW0880)	
ferric oxide red (UNII: 1K09F3G675)	
ferric oxide yellow (UNII: EX438O2MRT)	
ferrosoferric oxide (UNII: XM0M87F357)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-070-01	1 in 1 CARTON	12/01/2011	
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	12/01/2011	

Labeler - CLINIQUE LABORATORIES LLC (044475127)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(49527-070) , REPACK(49527-070)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(49527-070)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(49527-070)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(49527-070)

Establishment			
Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(49527-070)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(49527-070) , REPACK(49527-070)

Establishment			
Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(49527-070) , REPACK(49527-070)

Establishment			
Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(49527-070)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(49 527-070)

Revised: 1/2019

CLINIQUE LABORATORIES LLC