

**REDNESS SOLUTIONS DAILY PROTECTIVE BASE BROAD SPECTRUM SPF 15- titanium dioxide and zinc oxide 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.*

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**REDNESS SOLUTIONS DAILY PROTECTIVE BASE BROAD SPECTRUM SPF 15**

***Drug Facts***

**Active ingredients**

Titanium dioxide 6.5%

Zinc oxide 2.5%

**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 • octyldodecyl neopentanoate • c12-15 alkyl benzoate • butylene glycol • tricaprylyl citrate • steareth-2 trioctyldodecyl citrate • glyceryl stearate • peg-100 stearate •

barium sulfate • silica • ascophyllum nodosum extract • asparagopsis armata extract • sea whip extract • tocopheryl acetate • sucrose • pantethine • caffeine • dimethicone • cetearyl alcohol • isostearic acid • polyhydroxystearic acid • bisabolol • magnesium ascorbyl phosphate • lactobacillus ferment • sodium hyaluronate • sorbitol • phytosphingosine • caprylyl glycol • aluminum hydroxide • stearic acid • hexylene glycol • xanthan gum • disodium edta • phenoxyethanol • iron oxides (ci 77491, ci 77492, ci 77499) • chromium hydroxide green (ci 77289) [iln39531]

### **Other information**

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

### **PRINCIPAL DISPLAY PANEL - 40 ml Bottle Carton**

redness

CLINIQUE

redness  
solutions

daily  
protective base  
broad spectrum  
SPF 15

ALL SKIN TYPES

1.35 FL.OZ.LIQ./40 ml e

1,2,3,4  
ALL SKIN TYPES

CULTECH INC

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- use a water resistant sunscreen if swimming or sweating

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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:

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**Drug Facts**  
(continued)

**Inactive ingredients**

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**Other information**

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

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NEW YORK, N.Y. 10022  
LONDON W1K 3BD  
MADE IN U.S.A.  
6LJ4

clinique.com



redness



CLINIQUE

redness solutions

daily protective base broad spectrum SPF 15

ALL SKIN TYPES

1.35 FL.OZ./40 ml e

**Allergy Tested. 100% Fragrance Free. Ophthalmologist Tested.**

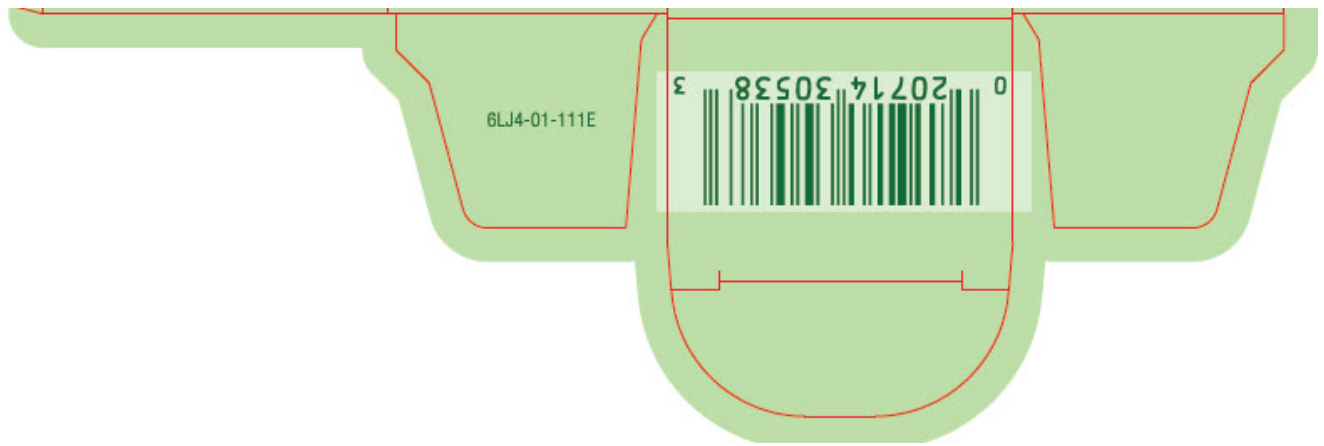
**No chemical sunscreens.**

Extra-gentle, physical, broad-spectrum daily protection from UVA/UVB exposure that can aggravate skins with Rosacea or reactive redness. Comforting makeup primer immediately corrects redness and evens skin tone with a sheer green tint. Oil-free. See enclosure.



004164





## REDNESS SOLUTIONS DAILY PROTECTIVE BASE BROAD SPECTRUM SPF 15

titanium dioxide and zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49527-019
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.0698 g in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0268 g in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>water</b> (UNII: 059QF0K00R)	
<b>methyl trimethicone</b> (UNII: S73ZQ10GXM)	
<b>octyldodecyl neopentanoate</b> (UNII: X8725R883T)	
<b>alkyl (c12-15) benzoate</b> (UNII: A9EJ3J61HQ)	
<b>butylene glycol</b> (UNII: 3XUS85K0RA)	
<b>tricaprylyl citrate</b> (UNII: BXW1GAI4TA)	
<b>glyceryl monostearate</b> (UNII: 230OU9XXE4)	
<b>peg-100 stearate</b> (UNII: YD01N1999R)	
<b>barium sulfate</b> (UNII: 25BB7EKE2E)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>pseudoptergorgia elisabethae</b> (UNII: UDY3H10UX5)	
<b>sucrose</b> (UNII: C151H8M554)	
<b>pantethine</b> (UNII: 7K81IL792L)	
<b>caffeine</b> (UNII: 3G6A5W338E)	
<b>dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)	
<b>isostearic acid</b> (UNII: X33R8U0062)	
<b>levomenol</b> (UNII: 24WE03BX2T)	
<b>magnesium ascorbyl phosphate</b> (UNII: 0R822556M5)	

<b>lactobacillus reuteri</b> (UNII: 9913I24QEE)
<b>hyaluronate sodium</b> (UNII: YSE9PPT4TH)
<b>sorbitol</b> (UNII: 506T60A25R)
<b>phytosphingosine</b> (UNII: GIN46U9Q2Q)
<b>caprylyl glycol</b> (UNII: 00YIU5438U)
<b>aluminum hydroxide</b> (UNII: 5QB0T2IUN0)
<b>stearic acid</b> (UNII: 4ELV7Z65AP)
<b>hexylene glycol</b> (UNII: KEH0A3F75J)
<b>xanthan gum</b> (UNII: TTV12P4NEE)
<b>edetate disodium anhydrous</b> (UNII: 8NLQ36F6MM)
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)
<b>ferric oxide red</b> (UNII: 1K09F3G675)
<b>ferric oxide yellow</b> (UNII: EX438O2MRT)
<b>ferrosoferric oxide</b> (UNII: XM0M87F357)
<b>chromium hydroxide green</b> (UNII: RV8FT8XF5R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-019-01	1 in 1 CARTON	12/01/2011	
1		40 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 INC. (173047747)

### Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(49527-019) , REPACK(49527-019)

### Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(49527-019)

### Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(49527-019)

### Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(49527-019)

### Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(49527-019)

### Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(49527-019) , REPACK(49527-019)

### Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(49527-019) , REPACK(49527-019)

### Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(49527-019)

### Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(49527-019)

Revised: 1/2019

CLINIQUE LABORATORIES INC.