# ALL CALM CLINICAL REDNESS CORRECTOR SPF 50- titanium dioxide and zinc oxide liquid

## Colorescience

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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# All Calm™ Clinical Redness Corrector SPF 50

# **Drug Facts**

Active ingredients	Purpose
Titanium Dioxide 11.6%	Sunscreen
Zinc Oxide 8.6%	Sunscreen

## Uses

- Helps prevent sunburn.
- If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

# 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 swallowed, get medical help or contact a Poison Control Center right away.

# **Directions**

- Apply liberally 15 minutes before sun exposure. Works best on moisturized skin.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months: Ask a doctor.
- **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.

# Inactive ingredients

Cyclopentasiloxane, Caprylic/Capric Triglyceride, Water/Aqua/Eau, Dimethicone Crosspolymer, Niacinamide, Disteardimonium Hectorite, Dimethicone/Vinyl Dimethicone Crosspolymer, Propylene Carbonate, Disodium Lauriminodipropionate Tocopheryl Phosphates, Crithmum Maritimum Extract, Magnolia Officinalis Bark Extract, Zingiber Officinale (Ginger) Root Extract, Magnesium Carboxymethyl Beta-Glucan, Jojoba Esters, Bisabolol, Silica, Polyhydroxystearic Acid, Dimethiconol, Alumina, Glyceryl Behenate/Eicosadioate, Phenoxyethanol, Triethoxycaprylylsilane, Ethylhexylglycerin, Tocopherol, Dehydroacetic Acid, Benzoic Acid, Glycolic Acid, Chloroacetic Acid, Chromium Oxide Greens (CI 77288), Iron Oxides (CI 77491, CI 77492, CI 77499).

## Other information

Protect this product from excessive heat and direct sun.

# Questions or comments?

Call toll free 866.426.5673

Dist. in USA by **colore**science<sup>®</sup> Carlsbad, CA 92011

# PRINCIPAL DISPLAY PANEL - 30 mL Tube Carton

**colore**science®

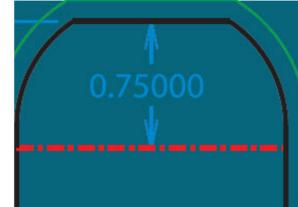
ALL CALM™

CLINICAL REDNESS CORRECTOR

Instantly neutralizes redness Soothes sensitive skin

50 Broad Spectrum SPF 50 Sunscreen PA++++

1 fl. oz. / 30 mL





ALL CALM® SPF 50

# <u>colorescience</u>

# For USA only

# Drug Facts (continued)

# Inactive ingredients

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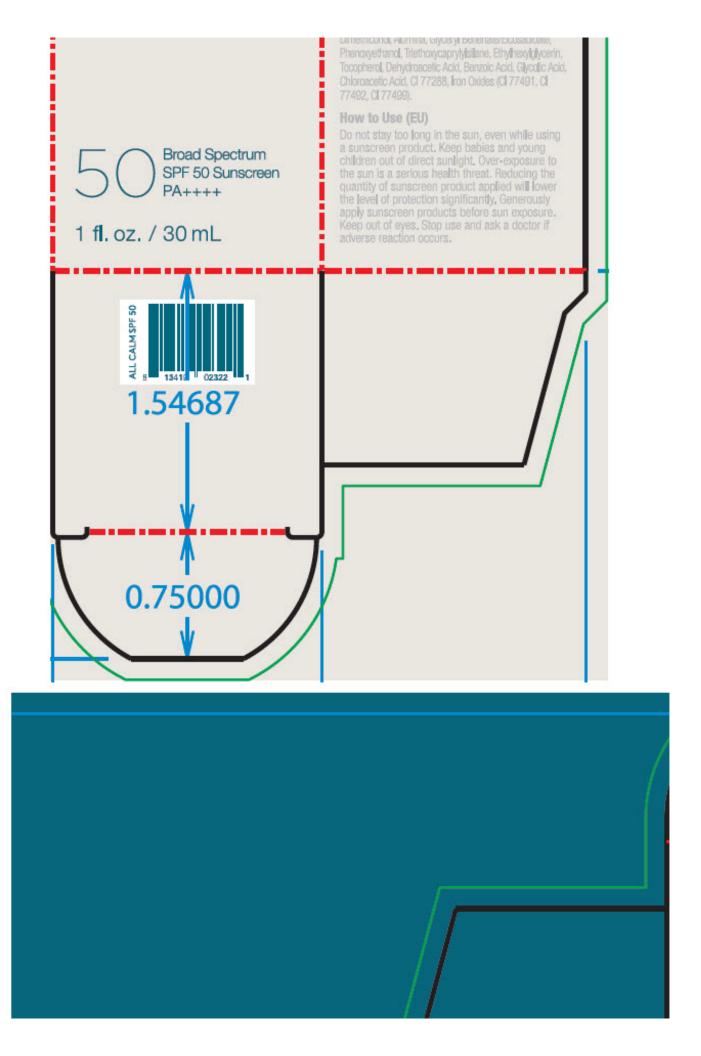
# **ALL CALM®**

# CLINICAL REDNESS CORRECTOR

Instantly neutralizes redness Soothes sensitive skin

### Ingredients (EU)

Cyclopentasiloxane, Caprylic/Capric Triglyceride, Titanium Dioxide, Zinc Oxide, Dimethicone Crosspolymer, Aqua/Water, Niacinamide, Dimethicone/Vinyl Dimethicone Crosspolymer, Disteardimonium Hectorite, Propylene Carbonate, Disodium Lauriminodipropionate Tocopheryl Phosphates, Crithmum Maritimum Extract, Magnolia Officinalis Bark Extract, Zingiber Officinale (Ginger) Root Extract, Magnesium Carboxymethyl Beta-Glucan, Jojoba Esters, Bisabolol, Silica, Polyhydroxystearic Acid,



# Find Your Calm

This 3-in-1 proprietary formula instantly neutralizes the appearance of redness, helps soothe and calm sensitive skin, and provides SPF 50 protection while its patent pending BioSolace® complex helps provide ongoing relief from sensitivity and the appearance of redness.

## Experience the confidence and ease of Colorescience®

- + Trusted and personally used by thousands of physicians.
- + 365-day defense from UV rays and environmenta stressors.

#### **How to Use**

Apply liberally to a moisturized face ensuring even coverage as the first step in your makeup application and 15 minutes before sun exposure. Store at room temperature.

Discover our full line of uncompromising, health-forward products designed to fit your life at colorescience.com

colorescience<sup>6</sup> Carlsbad, CA 92011 Made in USA | Fab aux É-U.

UK: London WC2H 9JQ, GB





# For USA only

# **Drug Facts**

# Active ingredients

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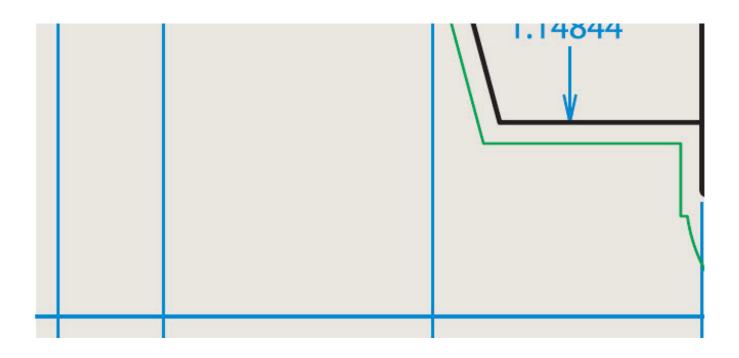
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titanium dioxide and zinc oxide liquid

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:68078-023

**Route of Administration** TOPICAL

# Active Ingredient/Active Moiety

Ingredient Name	<b>Basis of Strength</b>	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	116 mg in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	86 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
Niacinamide (UNII: 25X51I8RD4)	
Disteardimonium Hectorite (UNII: X687XDK09L)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
Propylene Carbonate (UNII: 8D08K3S51E)	
DISODIUM LAURIMINODIPROPIONATE TOCOPHERYL PHOSPHATES (UNII: 0K5Y9U1P6M)	
CHROMIC OXIDE (UNII: X5Z09SU859)	
ALUMINUM OXIDE (UNII: LMI2606933)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

DIMETHICONOL (100000 CST) (UNII: OSA9UP217S)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
JOJOBA OIL (UNII: 724GKU717M)	
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	
Glyceryl Behenate/Eicosadioate (UNII: 73CJJ317SR)	
LEVOMENOL (UNII: 24WE03BX2T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
CRITHMUM MARITIMUM WHOLE (UNII: J7IHY79BKY)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
Tocopherol (UNII: ROZB2556P8)	
MAGNOLIA OFFICINALIS BARK (UNII: 5M609NV974)	
Benzoic Acid (UNII: 8SKN0B0MIM)	
GINGER (UNII: C5529G5JPQ)	
Dehydroacetic Acid (UNII: 2KAG279R6R)	
Glycolic Acid (UNII: 0WT12SX38S)	
Chloroacetic Acid (UNII: 5GD84Y125G)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68078-023- 24	1 in 1 CARTON	08/02/2017	
1		30 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68078-023- 02	1 mL in 1 PACKET; Type 0: Not a Combination Product	08/02/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	08/02/2017	

# Labeler - Colorescience (128731929)

Revised: 10/2021 Colorescience