# CALMING PERFECTOR SPF 20 SUNSCREEN- 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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### Calming Perfector SPF 20 Sunscreen

### **Drug Facts**

Active ingredients	Purpose
Titanium Dioxide 5.4%	Sunscreen
Zinc Oxide 5.4%	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:
  - After 40 minutes of swimming or sweating.
  - Immediately after towel drying.
  - At least every 2 hours.
- 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, Dimethicone Crosspolymer, Glycerin, Water, Dimethicone/Vinyl Dimethicone Crosspolymer, Cucumis Sativus (Cucumber) Fruit Extract, Spirulina Maxima Extract, Camellia Sinensis Leaf Extract, Opuntia Ficus-Indica Stem Extract, Palmaria Palmata Extract, Disodium Lauriminodipropionate Tocopheryl Phosphates, Citrus Paradisi (Grapefruit) Seed

Extract, Ascorbic Acid, Dimethiconol, Dimethicone, Triethoxycaprylylsilane, Benzoic Acid, Dehydroacetic Acid, Phenoxyethanol, 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

Distributed in USA by Colorescience<sup>®</sup> Carlsbad, CA 92011

### PRINCIPAL DISPLAY PANEL - 30 mL Tube Carton

**colore**science<sup>®</sup>

CALMING PERFECTOR

3-IN-1 FACE PRIMER

Neutralizes redness

Soothes & nourishes skin

Water resistant (40 minutes)

20 Broad Spectrum SPF 20 Sunscreen

1 fl. oz. / 30 mL



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### Drug Facts (continued)

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### Other information:

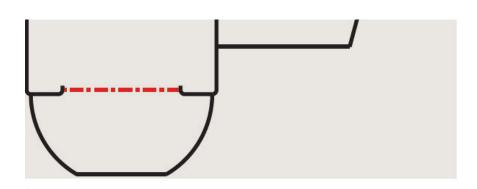
· Protect this product from excessive

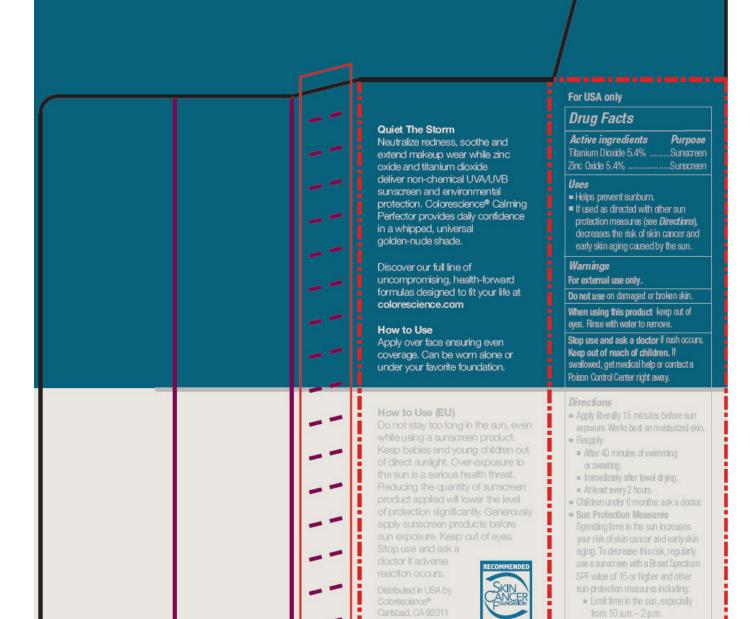
Questions or comments?

### Ingredients (EU)

Oyclopentasiloxane, Caprylic/Capric Triglyceride, Dimethicone Crosspolymer, Titanium Dioxide, Zinc Oxide, Glycerin, Aqua, Dimethicone/Vinyl Dimethicone Spirulina Maxima Extract, Camellia Sinensis Extract, Palmaria Palmata Extract, Disodium Phosphates, Citrus Paradisi Seed Extract, Ascorbic Acid, Dimethiconal, Dimethicone, Dehydroacetic Acid, Phenoxyethanol,

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 Wear long-sleeved shirts, pants, hats, and sunglasses.

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## **CALMING PERFECTOR SPF 20 SUNSCREEN**

titanium dioxide and zinc oxide liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68078-017
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Titanium Dioxide (UNII: 15FIX9 V2JP) (Titanium Dioxide - UNII:15FIX9 V2JP)	Titanium Dioxide	54 mg in 1 mL	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	54 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Dimethicone Crosspolymer (450000 MPA.S at 12% in Cyclopentasiloxane) (UNII: UF7620L1W6)	
Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0KO0R)	
Dimethicone/Vinyl Dimethicone Crosspolymer (Soft Particle) (UNII: 9E4CO0W6C5)	
Cucumber (UNII: YY7C30VXJT)	
Arthrospira Maxima (UNII: 9K7IG15M0Q)	
Green Tea Leaf (UNII: W2ZU1RY8B0)	
Opuntia Ficus-Indica Stem (UNII: MUD8892KHL)	
Dulse (UNII: 7832HOY4ZQ)	
Disodium Laurimino dipropionate To copheryl Phosphates (UNII: 0K5Y9U1P6M)	
Citrus Paradisi Seed (UNII: 12F08874Y7)	
Ascorbic Acid (UNII: PQ6CK8PD0R)	
Dimethiconol (100000 CST) (UNII: OSA9UP217S)	
Dimethicone (UNII: 92RU3N3Y1O)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Benzoic Acid (UNII: 8SKN0B0MIM)	
Dehydroacetic Acid (UNII: 2KAG279R6R)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Ferrosoferric Oxide (UNII: XM0M87F357)	

## **Packaging**

#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:68078-017-18	1 in 1 CARTON	0 2/0 1/20 17	
1		30 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68078-017-02	1 mL in 1 PACKET; Type 0: Not a Combination Product	02/01/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	0 2/0 1/20 17	

# Labeler - Colorescience (128731929)

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