

SPF 20 LOOSE MINERAL FOUNDATION- titanium dioxide and zinc oxide powder **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.

SPF 20 Loose Mineral Foundation

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Titanium Dioxide 18.6%	Sunscreen
Zinc Oxide 5.9%	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 80 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

Mica, Methicone, Calcium Silicate, Dimethicone, Triethoxycaprylylsilane, Sodium Sulfate, Bismuth Oxychloride (CI 77163), 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

Manufactured by
Colorescience®
Carlsbad, CA 92011

PRINCIPAL DISPLAY PANEL - 6 g Tube Carton

colorescience®

LOOSE
MINERAL
FOUNDATION

Breathable formula
Self-dispensing brush
Water resistant
(80 minutes)

20
Broad Spectrum
SPF 20
Sunscreen

Net Wt. 6 g / 0.21 oz.

0.62500



LOOSE MINERAL FOUNDATION
SPF 20

0.90625

For USA only

Drug Facts

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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.

For USA only

Drug Facts (continued)

Inactive Ingredients:

Mica, Methicone, Calcium Silicate, Dimethicone, Triethoxycaprylylsilane, Sodium Sulfate, Bismuth Oxychloride (CI 77163), Chromium Oxide Greens (CI 77288), Iron Oxides (CI 77491, CI 77492, CI 77499)

Other information:

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Questions or comments?

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colorescience®

LOOSE
MINERAL
FOUNDATION

Ingredients (EU)

Mica, Titanium Dioxide, Zinc Oxide, Methicone, Calcium Silicate, Dimethicone, Triethoxycaprylylsilane, Sodium Sulfate, [+/- CI 77163, CI 77288, CI 77491, CI 77492, CI 77499, CI 77891]

Directions

- Apply liberally 15 minutes before sun exposure. Works best on moisturized skin.
- Reapply:
 - After 80 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:

Breathable formula
Self-dispensing brush
Water resistant
(80 minutes)

How to Use (EU)

Do not stay too long in the sun, even while using a sunscreen product. Keep babies and young children out of direct sunlight. Over-exposure to the sun is a serious health threat. Reducing the quantity of sunscreen product applied will lower the level of protection significantly. Generously apply sunscreen products before sun exposure. Keep out of eyes. Stop use and ask a doctor if adverse reaction occurs.

- Limit time in the sun, especially from 10 a.m. – 2 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses.

Continued on opposite side panel ▶

20 Broad Spectrum
SPF 20
Sunscreen

Net Wt. 6 g / 0.21 oz.

1.18750

0.62500

MachineScore

MACHINE SCORE

Embrace the Brush

Take the mess out of minerals with Colorescience® Loose Mineral Foundation Brush. Self-dispensing sheer to medium foundation coverage and non-chemical UVA/UVB sunscreen and environmental protection in one simple, convenient application.

Experience the confidence and ease of Colorescience®

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

How to Use

Sweep generously and evenly on the skin prior to sun exposure. Reapply at least every two hours. See insert for more details.



SPF 20 LOOSE MINERAL FOUNDATION

titanium dioxide and zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68078-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	186 mg in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	59 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Mica (UNII: V8A1AW0880)	
Bismuth Oxychloride (UNII: 4ZR792I587)	
Dimethicone (UNII: 92RU3N3Y1O)	
Methicone (20 CST) (UNII: 6777U11MKT)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Calcium Silicate (UNII: S4255P4G5M)	
Chromic Oxide (UNII: X5Z09SU859)	
Sodium Sulfate (UNII: 0YPR65R21J)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Ferrosoferric Oxide (UNII: XM0M87F357)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68078-000-01	1 in 1 CARTON	10/01/2015	
1		6 g in 1 TUBE, WITH APPLICATOR; 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	10/01/2015	

Labeler - Colorescience (128731929)

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