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

Active ingredients	Purpose
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

For USA only

Drug Facts

Active ingredients Purpose
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:

colorescience

LOOSE MINERAL FOUNDATION

For USA only

Drug Facts (continued)

Inactive ingredients:

Mica, Methicone, Calcium Silicate, Dimethicone, Triethoxycapryfylsilane, Sodium Sulfate, Bismuth Oxychloride (CL77163), Chromium Oxide Greens (CL77288), Iron Oxides (CL77491, CL77492, CL77499)

Other information:

 Protect this product from excessive heat and direct sun.

Questions or comments? Call toll free 866.426.5673

Ingredients (EU)

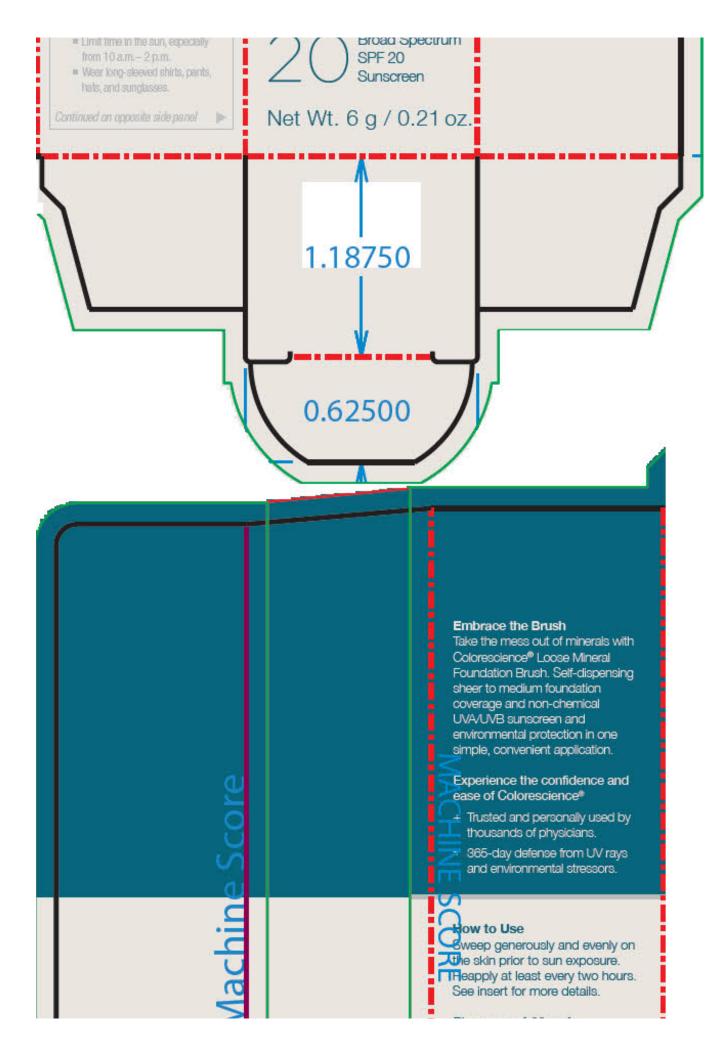
Mica, Titanium Dioxide, Zinc Oxide, Methicone, Calcium Silicate, Dimethicone, Triethoxycaprylylsilane, Sodium Sulfate, [+/- Cl 77163, Cl 77288, Cl 77491, Cl 77492, Cl 77499, Cl 77891]

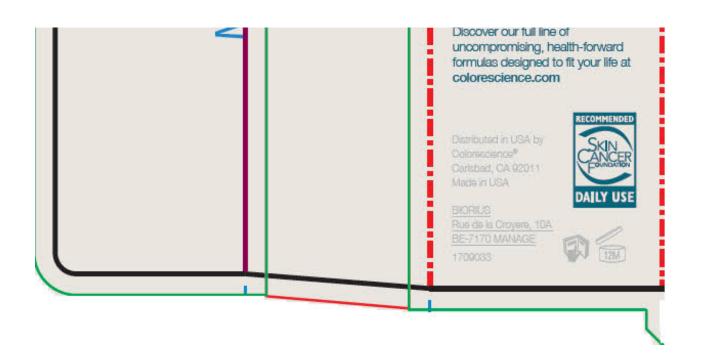
Breathable formula Self-dispensing brush

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.





SPF 20 LOOSE MINERAL FOUNDATION

titanium dioxide and zinc oxide powder

Product Information	Proc	luct	Informati	on
----------------------------	------	------	-----------	----

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: EX43802MRT)			

P	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, WTH APPLICATOR; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation		
OTC MONOGRAPH NOT FINAL	part352	10/01/2015	

Labeler - Colorescience (128731929)

Revised: 12/2021 Colorescience