

PIPETTE MINERAL SUNSCREEN BROAD SPECTRUM SPF50- zinc oxide lotion
Amyris, 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.

Active Ingredients

Zinc Oxide 20%

Purpose

Sunscreen

Uses

Helps prevent sunburn

if used as directed with other sun protection measures(see **directions**), decreases the risk of skin cancer and early signs of 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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply generously 15 minutes before sun exposure
- reapply at least every 2 hours
- **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 value of SPF 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
- use a water-resistant sunscreen if swimming or sweating
- children under 6 months of age:ask a doctor.

Inactive ingredients

Water, Caprylic/Capric Triglyceride, Glycerin, Squalane, Cetearyl Alcohol, Methyl Dihydroabietate, Sorbitan Olivatate, Cetyl Palmitate, Coco-Glucoside, Ethyl Ferulate, Bisabolol, Hydroxyacetophenone, Isostearic Acid, Lecithin, Polyglyceryl-3 Polyricinoleate, Polyhydroxystearic Acid, Caprylyl/Capryl Glucosides, 1,2-Hexandiol, Caprylyl Glycol, Physalis Angulata Extract, Acacia Senegal Gum, Xanthan Gum, Sodium Gluconate.

**Mineral Sunscreen
Broad Spectrum
SPF 50**

Fragrance Free
Clean · Nontoxic · Non-nano




120 ml / 4 fl oz

Dermatologist Tested · Hypoallergenic

Our baby-friendly sunscreen uses 100% mineral, non-nano zinc oxide for broad-spectrum UVA/UVB protection that works for the whole family. This lightweight formula rubs in easily (no ghostly white cast—seriously!), protecting from the sun's harmful rays.

Drug Facts				
<table style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: left;">Active Ingredients</th> <th style="text-align: left;">Purpose</th> </tr> <tr> <td>Zinc Oxide 20%</td> <td>Sunscreen</td> </tr> </table>	Active Ingredients	Purpose	Zinc Oxide 20%	Sunscreen
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Zinc Oxide 20%	Sunscreen			
<p>Uses</p> <p>■ 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</p>				
<p>Warnings</p> <p>■ 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.</p>				
<p>Directions</p> <p>■ apply generously 15 minutes before sun exposure. ■ children under 6 months of age: 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 ■ reapply at least every 2 hours ■ use a water-resistant sunscreen if swimming or sweating</p>				
<p>Inactive Ingredients Water, Caprylic/Capric Triglyceride, Squalane, Glycerin, Cetearyl Alcohol, Methyl Dihydroabietate, Sorbitan Olivatate, Cetyl Palmitate, Coco-Glucoside, Ethyl Ferulate, Caprylyl/Capryl Glucoside, Lecithin, Bisabolol, Physalis Angulata Extract, Xanthan Gum, Acacia Senegal Gum, Sodium Gluconate, Isostearic Acid, Polyhydroxystearic Acid, 1,2-Hexandiol, Polyglyceryl-3 Polyricinoleate, Hydroxyacetophenone, Caprylyl Glycol</p>				
<p>Other information Protect the product in this container from excessive heat and direct sun</p>				
<p>Questions or comments? Call 855-747-2229</p>				

Made in USA of domestic and foreign components.
Distributed by: Amryis Clean Beauty, Inc, Emeryville, CA 94608
pipettebaby.com



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PIPETTE MINERAL SUNSCREEN BROAD SPECTRUM SPF50

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73517-382
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	20 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
SQUALANE (UNII: GW89575KF9)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
COCO GLUCOSIDE (UNII: ICS790225B)	
ETHYL FERULATE (UNII: 5B8915UELW)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CAPRYLYL/CAPRYL OLIGOGLUCOSIDE (UNII: E00JL9G9K0)	
ACACIA SENEGAL WHOLE (UNII: QP4QYZ033C)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
BISABOLOL OXIDE A (UNII: 16AE65F94Y)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
HEXANEDIOL (UNII: ZIA319275I)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHYSALIS ANGULATA (UNII: W4TKW9D5GG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73517-382-01	120 mL in 1 TUBE; Type 0: Not a Combination Product	06/01/2020	
2	NDC:73517-382-02	30 mL in 1 TUBE; Type 0: Not a Combination Product	06/01/2020	
3	NDC:73517-382-03	15 mL in 1 TUBE; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	06/01/2020	

