

TINTED MINERAL FACE SUNSCREEN STICK - CREME- tinted mineral face sunscreen stick - creme stick

Private Label Select Ltd CO

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.

Beauty By Earth Tinted Mineral Face Sunscreen Stick - Creme

Dosage & Administration

<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Non-Nano Uncoated Zinc Oxide 20%.....</td> <td>Sunscreen</td> </tr> </tbody> </table> <p>Uses Helps prevent sunburn • Decreases the risk of skin cancer and early skin aging caused by the sun if used as directed with other sun protection measures (see directions).</p> <p>Inactive Ingredients Caprylic/Capric Triglyceride*, Helianthus Annuus (Sunflower) Seed Oil*, Cera Alba (Beeswax)*, Euphorbia Cerifera (Candelilla) Wax, Copernicia Cerifera (Carnauba) Wax*, Butyrospermum Parkii (Shea) Butter*, Ricinus Communis (Castor) Seed Oil*, Tocopherol (Sunflower Derived), Theobroma Cacao (Cocoa) Seed Butter*, Aloe Barbadensis Leaf Juice (Aloe Vera) Powder*, Mica (Ci:77019), Iron Oxides (Ci:77492) (Ci:77491) (Ci:77499) *Certified Organic Ingredient</p> <p>PEEL BACK FOR DRUG FACTS</p>	Active Ingredients	Purpose	Non-Nano Uncoated Zinc Oxide 20%.....	Sunscreen	<p>Drug Facts (continued)</p> <p>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.</p> <p>Directions Apply generously 15 minutes before sun exposure. Apply to all skin exposed to the sun. For children under 6 months of age: ask a doctor. Reapply: • After 80 minutes of swimming or sweating • Immediately after towel drying • At least every 2 hours</p> <p>Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging.</p>	<p>Drug Facts (continued)</p> <p>To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:</p> <ul style="list-style-type: none"> • Limit time in the sun, especially from 10 a.m. -2 p.m. • Wear long-sleeved shirts, pants, hats, and sunglasses <p>Protect the product in this container from excessive heat and direct sun.</p> <p>Manufactured for and distributed by: Beauty by Earth Flower Mound, TX 75028 www.beautybyearth.com</p> <p>Certified to NSF / ANSI 305 by QAI</p> <p>8 50003 96837 7 © 2020 Beauty by Earth. All rights reserved.</p>
Active Ingredients	Purpose					
Non-Nano Uncoated Zinc Oxide 20%.....	Sunscreen					

Warnings Section

Drug Facts (continued)

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Inactive Ingredients




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*Certified Organic Ingredient

Indications and Usage


Drug Facts	
Active Ingredients	Purpose
Non-Nano Uncoated Zinc Oxide 20%.....	Sunscreen
Uses Helps prevent sunburn	
• Decreases the risk of skin cancer and early skin aging caused by the sun if used as directed with other sun protection measures (see directions).	
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PEEL BACK FOR DRUG FACTS

Drug Facts (continued)
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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. Apply to all skin exposed to the sun. For children under 6 months of age: ask a doctor.
Reapply:
• After 80 minutes of swimming or sweating
• Immediately after towel drying
• At least every 2 hours
Sun Protection Measures.
Spending time in the sun increases your risk of skin cancer and early skin aging.

Drug Facts (continued)
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 am -2pm.
• Wear long-sleeved shirts, pants, hats, and sunglasses
Protect the product in this container from excessive heat and direct sun.
Manufactured for and distributed by: Beauty by Earth Flower Mound, TX 75028 www.beautybyearth.com
Certified to NSF / ANSI 305 by QAI
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OTC - Keep out of Reach of Children

Keep out of reach of children.
If product is swallowed, get medical help or contact a Poison Control Center right away.

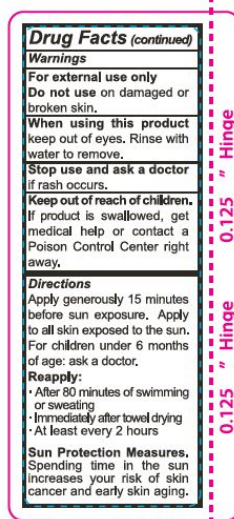
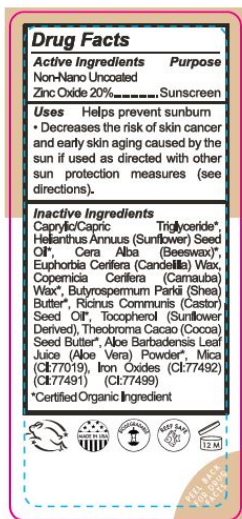
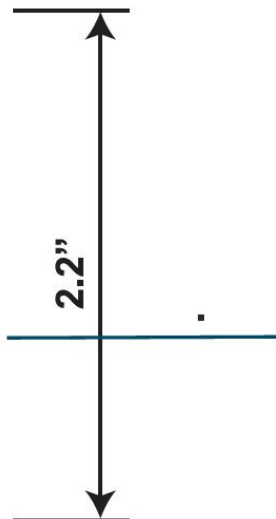
OTC Purpose

Active Ingredients	Purpose
Non-Nano Uncoated Zinc Oxide 20%.....	Sunscreen

OTC Active Ingredient

Active Ingredients	Purpose
Non-Nano Uncoated Zinc Oxide 20%.....	Sunscreen

Artwork - Front and Back Labels



Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62932-221
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20 g in 100 g	
Inactive Ingredients			
Ingredient Name	Strength		
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
CASTOR OIL (UNII: D5340Y2I9G)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
CARNAUBA WAX (UNII: R12CBM0EIZ)			
.ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9)			
.BETA.-TOCOPHEROL (UNII: 9U6A490501)			
SUNFLOWER OIL (UNII: 3W1JG795YI)			
CANDELILLA WAX (UNII: WL0328HX19)			
SHEA BUTTER (UNII: K49155WL9Y)			
FERROSO FERRIC OXIDE (UNII: XM0M87F357)			
COCOA BUTTER (UNII: 512OYT1CRR)			
WHITE WAX (UNII: 7G1J5DA97F)			
MICA (UNII: V8A1AW0880)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
FERRIC OXYHYDROXIDE (UNII: 87PZU03K0K)			
.GAMMA.-TOCOPHEROL (UNII: 8EF1Z1238F)			
.DELTA.-TOCOPHEROL (UNII: JU84X1H0N)			

Product Characteristics

Color	brown (Light Brown)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62932-221-33	14 g in 1 CONTAINER; Type 0: Not a Combination Product	12/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/28/2020	

Labeler - Private Label Select Ltd CO (005415463)

Revised: 12/2020

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