

SUNSCREEN- zinc oxide sunscreen 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.

Evanhealy Mocha - Dark Sheer Cover Stick SPF 30

Dosage & Administration

Directions

- Apply liberally 15 minutes before sun exposure.
- Reapply:
 - After 80 minutes of swimming or sweating
 - Immediately after towel drying
 - At least every 2 hours

Warnings Section

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 using and ask 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.

Inactive Ingredients

Inactive ingredients

Sunflower (Helianthus annuus) Seed Oil*, Coconut (Cocos nucifera) Oil*, Candelilla (Euphorbia cerifera) Wax*, Beeswax* (Cera alba), Argan (Argania spinosa) Kernel Oil*, Jojoba (Simmondsia chinensis) Seed Oil*, Red Raspberry (Rubus idaeus) Seed Oil*, Carnauba (Copernicia cerifera) Wax*, Orange (Citrus aurantium dulcis) Peel Oil*, Vanilla (Vanilla planifolia) Flavor*, Cocoa (Theobroma cacao) Seed Butter*, Shea (Butyrospermum parkii) Butter*, Tocopherol (Vitamin E). May Contain [+/-] Iron Oxides (CI 77491, CI 77492, CI 77499), Titanium dioxide (CI 77861).*ORGANIC

Indications and Usage

Active ingredient Zinc Oxide 20%	Purpose Sunscreen
Uses <ul style="list-style-type: none">• 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.	Directions <ul style="list-style-type: none">• Apply liberally 15 minutes before sun exposure.• Reapply:<ul style="list-style-type: none">• After 80 minutes of swimming or sweating• Immediately after towel drying• At least every 2 hours Sun Protection Measures <p>Spending time in the sun increases your risk of skin cancer and early signs of aging. To decrease this risk, regularly use a sunscreen with broad spectrum SPF 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-sleeve shirts, pants, hats, and sunglasses• Children under 6 months: Ask a doctor
Warnings <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 using and ask 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>	

Keep Out Of Reach of Children

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 using and ask 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.

OTC Purpose Section

Active ingredient

Zinc Oxide 20%

Purpose

Sunscreen

OTC Active Ingredients

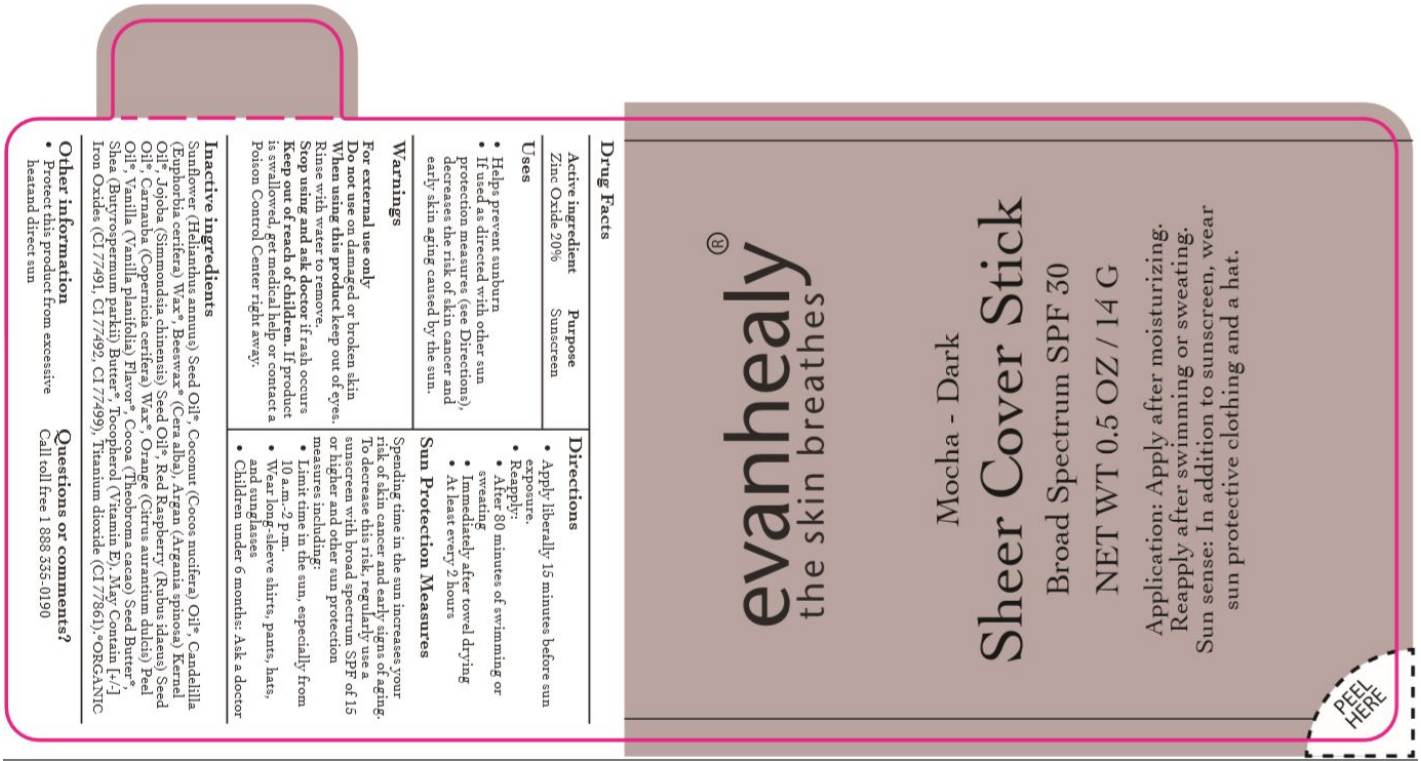
Active ingredient

Zinc Oxide 20%

Purpose

Sunscreen

Label for Container



SUNSCREEN			
zinc oxide sunscreen stick			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62932-208
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		
ORANGE OIL (UNII: AKN3KSD11B)			
JOJOBA OIL (UNII: 724GKU717M)			
COCONUT OIL (UNII: Q9L0O73W7L)			
WHITE WAX (UNII: 7G1J5DA97F)			
SUNFLOWER OIL (UNII: 3W1JG795YI)			
SHEA BUTTER (UNII: K49155WL9Y)			
CANDELILLA WAX (UNII: WL0328HX19)			
CARNAUBA WAX (UNII: R12CBM0EIZ)			
COCOA BUTTER (UNII: 512OYT1CRR)			
ARGAN OIL (UNII: 4V59G5UW9X)			
.BETA.-TOCOPHEROL (UNII: 9U6A490501)			
RASPBERRY SEED OIL (UNII: 9S8867952A)			

Product Characteristics

Color	brown (Earth Brown)	Score	
Shape		Size	
Flavor	VANILLA (Vanilla Bean Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62932-208-34	14 g in 1 CONTAINER; Type 0: Not a Combination Product	04/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/01/2019	

Labeler - Private Label Select Ltd CO (005415463)