

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.

DERMATOLOGIST TESTED
PARABEN FREE
SHEA BASED

PROMISE ORGANIC™

SPF30
COCONUT
SUNSCREEN
STICK

Natural Non-Nano Zinc Oxide
 Safe for Sensitive Skin
 Fragrance-Free
 Water Resistant (80 Minutes)

BROAD SPECTRUM SPF30
UVA/UVB PROTECTION

Contains Organic Ingredients
 Net Wt. 0.5 oz./ 14 g

PRESS DIRECTION

WE PROMISE PURITY

No Parabens, Harsh Sulfates, Silicones, Artificial Colorants or Synthetic Fragrances



Made in the USA. Distributed by Sensible Organics Inc.
 Certified to NSF/ANSI-305 by QAI
www.PromiseOrganic.com

Drug Facts

Active Ingredients	Purpose
Zinc Oxide 20%	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

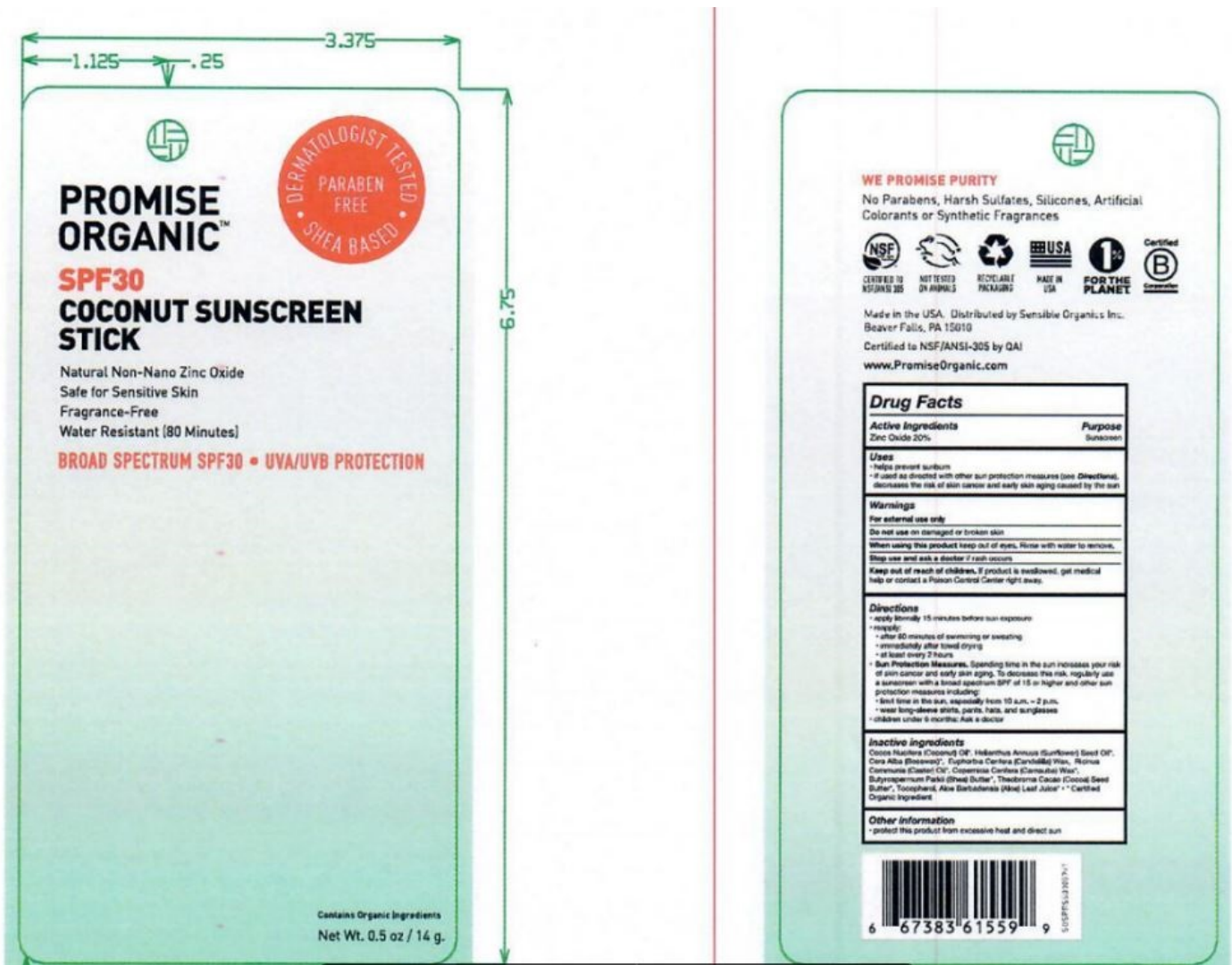
Warnings
For external use only
 Do not use on damaged or broken skin
When using this product keep out of eyes. Rinse with water to remove.
Stop use and ask a doctor if rash occurs
 Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

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
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 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-sleeve shirts, pants, hats, and sunglasses
 - children under 6 months: Ask a doctor

Inactive ingredients
 Helianthus Annuus (Sunflower) Seed Oil*, Ricinus Communis (Castor) Oil*, Olea Europaea (Olive) Oil*, Cera Alba (Beeswax)*, Cocos Nucifera (Coconut) Oil*, Simmondsia Chinensis (Jojoba) Oil*, Butyrospermum Parkii (Shea) Butter*, Tocopherol, * Certified Organic Ingredient

Other information
 - protect this product from excessive heat and direct sun





SUNSCREEN

zinc oxide sunscreen stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62932-152
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
SUNFLOWER OIL (UNII: 3W1JG795YI)	
SHEA BUTTER (UNII: K49155WL9Y)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
COCONUT OIL (UNII: Q9L0O73W7L)	

CASTOR OIL (UNII: D5340Y2I9G)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CANDELILLA WAX (UNII: WL0328HX19)	
COCOA BUTTER (UNII: 512OYT1CRR)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62932-152-19	1 in 1 BLISTER PACK	01/31/2016	
1		19 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/31/2016	

Labeler - Private Label Select Ltd CO (005415463)