PEOPLE4OCEAN SPF50 SUNSCREEN VEGAN- zinc oxide cream P4O Distribution Pty Ltd

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.

People4Ocean SPF50 sunscreen vegan

Drug Facts

Active ingredient

Zinc oxide 22.5%

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 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
- 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 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

• children under 6 months of age: Ask a doctor

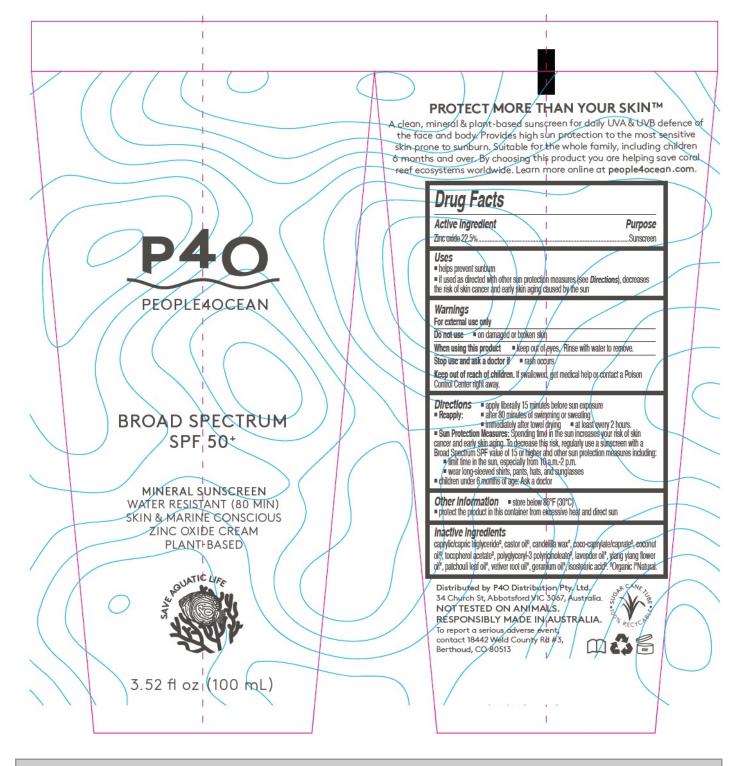
Other information

- store below 86°F (30°C)
- protect the product in this container from excessive heat and direct sun

Inactive ingredients

caprylic/capric triglyceride°, castor oil°, candelilla wax*, coco-caprylate/caprate°, coconut oil°, tocopherol acetate°, polyglyceryl-3 polyricinoleate°, lavender oil*, ylang ylang flower oil*, patchouli leaf oil*, vetiver root oil*, geranium oil*, isostearic acid°. °Organic |*Natural.

Package Labeling:



PEOPLE4OCEAN SPF50 SUNSCREEN VEGAN

zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73192-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	

ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)) ZINC CATION	225 mg in 1 mL
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Inactive Ingredients		
Ingredient Name	Strength	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
CASTOR OIL (UNII: D5340 Y2I9 G)		
CANDELILLA WAX (UNII: WL0328HX19)		
COCOYL CAPRYLOCAPRATE (UNII: 8D9H4QU99H)		
COCONUT OIL (UNII: Q9L0O73W7L)		
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)		
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)		
LAVENDER OIL (UNII: ZBP1YXW0H8)		
CANANGA OIL (UNII: 8 YO Y78 GNNX)		
GERANIUM O IL, ALGERIAN TYPE (UNII: 5Q1I94P4WG)		
ISOSTEARIC ACID (UNII: X33R8 U0062)		

Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:73192-020-00	100 mL in 1 TUBE; Type 0: Not a Combination Product	11/0 1/20 19	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/0 1/20 19	

Labeler - P4O Distribution Pty Ltd (745079594)

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