

**PEOPLE4OCEAN SPF50 SUNSCREEN- zinc oxide lotion**  
**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.*

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**People4Ocean SPF50 sunscreen**

***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 and evenly 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**

Purified water, Coco-Caprylate/Caprates, Caprylic/capric triglyceride°, Polyglyceryl-3 Polyricinoleate, Dimethicone, Octyl Palmitate, Isostearic Acid°, Butylene glycol, PEG-30 dipolyhydroxystearate, Beeswax°, Glycerol, Polyethylene, Phenoxyethanol, Glyceryl oleate, Ethylhexylglycerin, Lavender Oil\*, Ylang Ylang Flower Oil\*, Patchouli Leaf Oil\*, Vetiver Root Oil\*, Geranium Oil\*, Xanthan gum.  
°Organic | \*Natural.

**Package Labeling:**



**BROAD SPECTRUM  
SPF 50+**

MINERAL SUNSCREEN  
WATER RESISTANT (80 MIN)  
SKIN & MARINE CONSCIOUS  
ZINC OXIDE CREAM  
FACE & BODY



33.8 fl oz (1.06 qt) (1 L)

**PROTECT MORE THAN YOUR SKIN™**

A mineral, eco-conscious sunscreen for daily UVA & UVB protection of the face & body. By choosing this product, you are helping save coral reef ecosystems worldwide. Learn more online at [people4ocean.com](http://people4ocean.com).

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Zinc oxide 22.5%	Sunscreen
<b>Uses</b>	
<ul style="list-style-type: none"> <li>▪ helps prevent sunburn</li> <li>▪ if used as directed with other sun protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun</li> </ul>	
<b>Warnings</b>	
For external use only	
Do not use <ul style="list-style-type: none">▪ on damaged or broken skin</ul>	
When using this product <ul style="list-style-type: none">▪ keep out of eyes. Rinse with water to remove.</ul>	
Stop use and ask a doctor if <ul style="list-style-type: none">▪ rash occurs</ul>	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
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Distributed by P4O Distribution Pty. Ltd., 34 Church St, Abbotsford VIC 3067, Australia. To report a serious adverse event, contact 18442 Weld County Rd #3, Berthoud, CO 80513

RESPONSIBLY MADE IN AUSTRALIA. NOT TESTED ON ANIMALS.



**PEOPLE4OCEAN SPF50 SUNSCREEN**

zinc oxide lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73192-030
<b>Route of Administration</b>	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

## Inactive Ingredients

Ingredient Name	Strength
PEG-30 DIPOLYHYDROXYSTEARATE (4000 MW) (UNII: 9713Q0S7FO)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
CANANGA OIL (UNII: 8YOY78GNNX)	
GERANIUM OIL, ALGERIAN TYPE (UNII: 5Q1I94P4WG)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	
COCOYL CAPRYLOCAPRATE (UNII: 8D9H4QU99H)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73192-030-00	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/01/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/01/2019	

**Labeler** - P4O Distribution Pty Ltd (745079594)

Revised: 7/2020

P4O Distribution Pty Ltd