

PEOPLE4OCEAN SPF30 SUNSCREEN- 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 SPF30 Sunscreen

Drug Facts

Active ingredient

Zinc oxide 22%

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

caprylic/capric triglyceride, grape seed oil, beeswax, shea butter, candelilla wax, soybean oil, glyceryl isostearate, polyhydroxystearic acid, jojoba seed oil, tocopherol, safflower seed oil, english lavender oil, ylang ylang flower oil, patchouli leaf oil, vetiver root oil, geranium oil, cucumber fruit extract, carrot root extract, beta-carotene, rose hip fruit oil

Package Labeling:

P4O
PEOPLE4OCEAN

**BROAD SPECTRUM
SPF 30**

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






6.8 fl oz (200 mL)

PROTECT MORE THAN YOUR SKIN™

A 100% natural & mineral sunscreen for daily UVA & UVB defence of the face & body. Provides high sun protection to the most sensitive skin prone to sunburn. Suitable for the whole family, including children 6 months and over. By choosing this product, you are helping save coral reefs worldwide. Learn more online at people4ocean.com.

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Zinc oxide 22%	Sunscreen
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Warnings	
For external use only	
Do not use <input type="checkbox"/> on damaged or broken skin	
When using this product <input type="checkbox"/> keep out of eyes. Rinse with water to remove.	
Stop use and ask a doctor if <input type="checkbox"/> rash occurs	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
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Distributed by P4O Distribution Pty. Ltd.
34 Church St, Abbotsford VIC 3067, Australia.
NOT TESTED ON ANIMALS.
RESPONSIBLY MADE IN AUSTRALIA.
To report a serious adverse event,
contact 18442 Weld County IRd #3,
Berthoud, CO 80513

5mm Clear Ft

FRONT

RACK

PEOPLE4OCEAN SPF30 SUNSCREEN

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73192-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	220 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BETA CAROTENE (UNII: 01YAE03M7J)	
ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SHEA BUTTER (UNII: K49155WL9Y)	
CANDELILLA WAX (UNII: WL0328HX19)	
SOYBEAN OIL (UNII: 241ATL177A)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
JOJOBA OIL (UNII: 724GKU717M)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
CANANGA OIL (UNII: 8YOY78GNNX)	
VETIVER OIL (UNII: 9M9P32M01L)	
GERANIUM OIL, ALGERIAN TYPE (UNII: 5Q1I94P4WG)	
CARROT (UNII: L56Z1JK48B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73192-010-02	200 mL in 1 TUBE; Type 0: Not a Combination Product	05/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/01/2018	

Labeler - P4O Distribution Pty Ltd (745079594)

Revised: 5/2020

P4O Distribution Pty Ltd