

PHARMASKINCARE SOLAR-C MOISTURIZER SPF 50- octinoxate, zinc oxide lotion **Spa de Soleil**

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.

Pharmaskincare Solar-C Moisturizer SPF 50

Active Ingredients

Octinoxate 7.5%

Zinc Oxide 9.5%

Purpose

Sunscreen

Warnings

- For external use only.
- Do not use on broken or damaged skin
- When using this product, keep out of eyes. Rinse with water to remove.
- Stop use and ask a doctor if rash or irritation occurs or lasts.
- If swallowed, seek medical help or contact a poison control center right away.
- Keep out of reach of children.

Directions

Apply every morning as a daily moisturizer. Apply generously and evenly 15 minutes before sun exposure. Reapply at least every two hours. Use a water-resistant sunscreen if swimming or sweating. Children under six months of age: consult a doctor before use.

Other Information

Protect the product in this container from excessive heat.

Uses:

Helps prevent sunburn. Higher SPF gives more sunburn protection. If used as directed with other sun protection measures (see Sun Alert) decreases the risk of skin cancer and early skin aging caused by the sun.

Sun Alert: 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 such as limited time in the sun, especially from 10 a.m. to 2 p.m. Wear long pants, hats, sunglasses, and long-sleeve shirts.

Inactive Ingredients:

Water, Cocos Nucifera (Coconut) Oil, Carthamus Tinctorius (Safflower) Seed Oil, Cetyl Alcohol, Caprylic/Capric Triglyceride, Glycerin, Glyceryl Stearate, PEG-100 Stearate, Titanium Dioxide, Polyglyceryl-3 Beeswax, Polyglyceryl-6 Distearate, Jojoba Esters, Polyhydroxystearic Acid,

Carbomer, *CO Glycerin, Sodium Hydroxide, Thymus Vulgaris (Thyme) Leaf Extract, Rosa Canina Fruit Extract, Gardenia Florida Fruit Extract, Fucus Vesiculosus Extract, *CO Carum Petroselinum (Parsley) Extract, *CO Centella Asiatica Leaf Extract, *CO Cucumis Sativus (Cucumber) Seed Extract, *CO Daucus Carota Sativa (Carrot) Root Extract, *CO Euphrasia Officinalis Extract, Benzyl Alcohol, Disodium EDTA, Dehydroacetic Acid

Warning

Keep out of reach of children.

Pharmaskincare SolarC SPF 50.jpg

<p>Drug Facts</p> <p>Active Ingredients / Purpose: Zinc Oxide 9.5% Sunscreen Titanium Dioxide 7.5% Sunscreen</p> <p>Uses: Helps prevent sunburn. Higher SPF gives more sunburn protection. If used as directed with other sun protection measures (see Sun Alert), decreases the risk of skin cancer and early skin aging caused by the sun.</p> <p>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 or irritation occurs or lasts. • If swallowed, seek medical help or contact a poison control center right away. • Keep out of reach of children.</p> <p>Directions: Apply every morning as your daily moisturizer. Apply generously and evenly fifteen minutes before sun exposure. Reapply at least every two hours. Use a water-resistant sunscreen if swimming or sweating. Children under six months of age: Consult a doctor.</p> <p>Other Information: Protect the product in this container from excessive heat.</p> <p>Inactive Ingredients: Aqua, Cetea Myristea (Cocconut) Oil, Candelilla Wax, Tocopherol (Vitamin E), Caprylyl Glycol, Glycerin, Carbomer, Polysiloxane-4, Dimethylsiloxane, Titanium Dioxide, Jojoba Esters, Polyhydroxybutyrate, Carbomer, Polyglyceryl-3 Benzoin, *CO Glycerin, Sodium Hydroxide, Thymus Vulgaris (Thyme) Leaf Extract, Rosa Canina Fruit Extract, Gardenia Florida Fruit Extract, Fucus Vesiculosus Extract, *CO Carum Petroselinum (Parsley) Extract, *CO Centella Asiatica Leaf Extract, *CO Cucumis Sativus (Cucumber) Seed Extract, *CO Daucus Carota Sativa (Carrot) Root Extract, *CO Euphrasia Officinalis Extract, Ascorbic Acid (Vitamin C), Retinol Palmitate (Vitamin A), Tocopheryl Acetate (Vitamin E), Phenoxyethanol, Ethylhexylglycerin, Disodium EDTA. *Certified Organic</p> <p>Manufactured by Pharmaskincare® San Valley, CA 91252 USA</p> <p> MADE IN USA</p>
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Pharmaskincare® has been at the forefront of the beauty industry, its ground-breaking technology making way for an innovative and unique approach to addressing various skin conditions. Each collection is designed to fuse nature's potent restorative powers with scientifically advanced ingredients. Harnessing the benefits of certified organic botanical extracts, alpha hydroxy acids, advanced peptides, vitamins, and more, Pharmaskincare offers skin gentle and effective formulations that provide the best possible care for your skin. From adolescence to maturity, Pharmaskincare has designed products that will guide your skin through each stage.

Pharmaskincare® is committed to making products that are environmentally conscious and free of parabens, sulfates, dyes, mineral oils and lanolin.

PHARMASKINCARE®

ADVANCED SCIENCE®

SOLAR C

MOISTURIZER

S P F - 5 0

4 fl oz e 120 mL

Pharmaskincare® Solar C Moisturizer SPF-50 is an advanced, lightweight sunscreen that helps replenish moisture and promotes pH balance while protecting the skin from harmful sun rays. This formula is fortified with organic extracts to keep skin looking and feeling healthy and hydrated.

The Pharmaskincare® Advanced Science® Solar C collection is specifically designed to aid in skin protection and rejuvenation by fusing broad-spectrum SPF with natural minerals, coconut oil, and carrot extract. This ground-breaking technology results in unique products that not only protect the skin but also work to restore and enhance skin vitality.

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MOISTURIZER

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4 fl oz e 120 mL

Drug Facts

Active Ingredients / Purpose:
Zinc Oxide 9.5% Sunscreen
Titanium Dioxide 7.5% Sunscreen

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San Valley, CA 91252 USA

MADE IN USA

www.pharmaskincare.com

PHARMASKINCARE SOLAR-C MOISTURIZER SPF 50

octinoxate, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68062-9098
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.238 mg in 2.5 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.188 mg in 2.5 mL

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
WATER (UNII: 059QF0KO0R)	
COCONUT OIL (UNII: Q9L0O73W7L)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68062-9098-1	120 mL in 1 TUBE; Type 0: Not a Combination Product	10/10/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/10/2017	

Labeler - Spa de Soleil (874682867)

Establishment

Name	Address	ID/FEI	Business Operations
Spa de Soleil		874682867	manufacture(68062-9098)