

MOISTURE SUNSCREEN SPF 50- titanium dioxide, 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.

Moisturizer Sunscreen SPF 50

Active Ingredients

Zinc Oxide 9.5%

Octinoxate 7.5%

Purpose

Sunscreen

Warnings

Warnings When using this product

- keep out of the eye area
- rinse with water to remove
- stop use and ask a doctor if rash or irritation develops
- for external use only
- keep out of reach of children

Directions

Directions: Apply generously and evenly thirty 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.

Inactive Ingredients

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

Principal Display Panel

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 help skin look and feel healthy and hydrated.

Drug Facts

Active Ingredients:	Purpose:
Zinc Oxide 9.5%.....	Sunscreen
Octinoxate 7.5%.....	Sunscreen

Uses: ■ Helps prevent sunburn. ■ Higher SPF gives more sunburn protection. ■ If used as directed with other sun protection measures, 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 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 generously and evenly thirty 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.

Other Information: Protect the product in this container from excessive heat.

Inactive Ingredients: Aqua, Cocos Nucifera (Coconut) Oil, Carthamus Tinctorius (Safflower) Seed Oil, Heptyl Undecylenate, Caprylic/Capric Triglyceride, Cetyl Alcohol, Glycerin, Polyglyceryl-6 Distearate, Glyceryl Stearate, Titanium Dioxide, PEG-100 Stearate, Jojoba Esters, Polyhydroxystearic Acid, Polyvalcervyl-3 Beeswax.

Disodium EDTA, *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), Tocopheryl Acetate (Vitamin E), Retinyl Palmitate (Vitamin A), Carbomer, Phenoxyethanol, Ethylhexylglycerin. ***Certified Organic** SA11-V1

Manufactured for :

Made in USA



MOISTURE SUNSCREEN SPF 50

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68062-9001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	12.6 mg in 120 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	9 mg in 120 mL

Inactive Ingredients

Ingredient Name	Strength
HEPTYL UNDECYLENATE (UNII: W77QUB6GXO)	

SAFFLOWER OIL (UNII: 65UEH262IS)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCONUT OIL (UNII: Q9L0O73W7L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68062-9001-1	120 mL in 1 TUBE; Type 0: Not a Combination Product	09/09/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	09/09/2021	

Labeler - Spa de Soleil (874682867)

Establishment

Name	Address	ID/FEI	Business Operations
Spa de Soleil		874682867	manufacture(68062-9001)

Revised: 9/2021

Spa de Soleil