

## **NATURAL 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.*

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### **Natural SPF 50**

#### **Active Ingredients**

Titanium Dioxide 7.2%

Zinc Oxide 9.5%

#### **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

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Directions: for sunscreen use

- apply generously 15 minutes before sun exposure
- apply to all skin exposed to the sun
- children under 6 months of age: Ask a doctor

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#### **Inactive Ingredients**

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carthamus tinctorius (safflower) seed oil, coconut alkanes, coco caprylate/caprato, caprylic/capric triglyceride, stearic acid, alumina, polyhydroxystearic acid, helianthus annuus (sunflower) seed oil, pongamia glabra (karanja) seed oil, vitis vinifera (grape) seed oil, olea europaea (olive) oil, argania spinosa (argan) oil, oryza sativa (rice) bran extract, rosarinus officinalis (rosemary) extract, tocopherol, argania spinosa kernel oil,

tocopheryl acetate (vitamin E), bisabolol, squalane

## Principal Display Panel

PARABEN-FREE · SULFATE-FREE · FRAGRANCE-FREE · DYE-FREE  
 PETROLATUM-FREE · MINERAL-OIL FREE · LANOLIN-FREE · NON-NANO

# NATURAL SUNSCREEN SPF 50 +

3.3 fl oz | 100 mL

<b>Drug Facts</b>	
<b>Active Ingredients / Purpose:</b>	
Titanium Dioxide 7.2%.....	sunscreen
Zinc Oxide (Non-Nano) 9.5%.....	sunscreen
<b>Uses</b>	
■ Provides high protection against sunburn.	
<b>Warnings</b> When using this product:	
■ Keep out of the eye area. Rinse with water to remove.	
■ Stop usage and ask a doctor if rash or irritation develops.	
■ For external use only. ■ Keep out of the reach of children.	
<b>Directions</b>	
■ Shake before spraying. ■ Spray into hands to apply to face. ■ Apply thin layer over clean, dry skin. ■ Massage well. ■ Allow 15 minutes of complete penetration before sun exposure. ■ Reapply every 1-2 hours & after swimming or sweating. ■ Protect the product in this container from excessive heat.	
<b>Inactive Ingredients:</b>	
Carthamus Tinctorius (Safflower) Seed Oil, Coconut Alkanes (And) Coco-Caprylate/Caprate, Caprylic/Capric Triglyceride, Helianthus Annuus (Sunflower) Seed Oil, Vitis Vinifera (Grape) Seed Oil, *CO Pongamia Glabra Seed Oil, Olea Europaea (Olive) Fruit Oil, Argania Spinosa Kernel Oil, Stearic Acid, Polyhydroxystearic Acid, Tocopheryl Acetate (Vitamin E), Alumina, Oryza Sativa (Rice) Bran Extract, Bisabolol, Helianthus Annuus (Sunflower) Extract, **Squalane, Rosmarinus Officinalis (Rosemary) Leaf Extract, Tocopherol.	
*CO Certified Organic * From Sugarcane	NDC # 68062-8307-1 MSC106
<b>MANUFACTURED FOR:</b>	<b>MADE IN USA</b>
	 

## NATURAL SPF 50

titanium dioxide, zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68062-8307
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	780 mg in 118 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	900 mg in 118 mL

### Inactive Ingredients

Ingredient Name	Strength

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>ETHYL MACADAMIATE</b> (UNII: ANA2NCS6V1)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SQUALANE</b> (UNII: GW89575KF9)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68062-8307-1	118 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/04/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	05/04/2017	

**Labeler** - Spa de Soleil (874682867)

### Establishment

Name	Address	ID/FEI	Business Operations
Spa de Soleil		874682867	manufacture(68062-8307)

Revised: 12/2022

Spa de Soleil