

## **TRU SKIN RITUALS SPF 25- titanium dioxide, zinc oxide spray 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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### **Tru Skin Rituals SPF 25**

#### **Active Ingredients**

Titanium Dioxide 4.8%

Zinc Oxide 6.8%

#### **Purpose**

Sunscreen

#### **Warnings**

##### **Warnings**

- For external use only
- Do not use on damaged or broken skin
- Stop use and ask a doctor if rash occurs
- When using this product, keep out of eyes
- Rinse with water to remove
- **Keep out of reach of children**
- If swallowed, get medical help or contact a Poison Control Center right away

#### **Directions**

Directions

- Apply liberally 15 minutes before sun exposure
- Apply to all skin exposed to the sun

#### **Inactive Ingredients**

Inactive Ingredients:

Alumina, Argania Spinosa Kernel Oil, Bisabolol, Caprylic/Capric Triglyceride, Carthamus Tinctorius (Safflower) Seed Oil, Coconut Alkanes (And) Coco-Caprylate/Caprates, Helianthus Annuus (Sunflower) Extract, Helianthus Annuus (Sunflower) Seed Oil, Hydrogenated Castor Oil, Oryza Sativa (Rice) Bran Extract, Polyhydroxystearic Acid, Ricinus Communis (Castor) Seed Oil, Rosmarinus Officinalis (Rosemary) Leaf Extract, Sodium Hyaluronate (Hyaluronic Acid), Stearic Acid, Tocopherol, Tocopheryl Acetate (Vitamin E)

**Keep out of reach of children**

**DIRECTIONS:**

- Apply liberally 15 minutes before sun exposure
- Apply to all skin exposed to the sun

**Reapply:**

- after 40 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours

**espieve**

Espieve Body Spray

Sunscreen  
Broad Spectrum SPF 25

Reef Friendly • Cruelty-Free

<b>DRUG FACTS</b>	
<b>ACTIVE INGREDIENTS:</b> Titanium Dioxide (USP) 4.8% ..... Zinc Oxide (USP) 6.8%	<b>PURPOSE:</b> 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 Directions), decreases the risk of skin cancer and early aging caused by the sun</li> </ul>	
<b>WARNINGS:</b>	
<ul style="list-style-type: none"> <li>• For external use only</li> <li>• Do not use on damaged or broken skin</li> <li>• Stop use and ask a doctor if rash occurs</li> <li>• When using this product, keep out of eyes</li> <li>• Rinse with water to remove</li> <li>• <b>Keep out of reach of children</b></li> <li>• If swallowed, get medical help or contact a Poison Control Center right away</li> </ul>	
<b>DIRECTIONS:</b>	
<ul style="list-style-type: none"> <li>• Apply liberally 15 minutes before sun exposure</li> <li>• Apply to all skin exposed to the sun</li> </ul>	
<b>Reapply:</b>	
<ul style="list-style-type: none"> <li>• after 40 minutes of swimming or sweating</li> <li>• immediately after towel drying</li> <li>• at least every 2 hours</li> </ul>	
<b>Children under 6 months:</b> Ask a doctor	
<b>Sun Protection Measures:</b> 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:	
<ul style="list-style-type: none"> <li>• Limit time in the sun, especially from 10am – 2pm</li> <li>• Wear long-sleeved shirts, pants, hats, and sunglasses</li> </ul>	
<b>INACTIVE INGREDIENTS:</b>	
Alumina, Argania Spinosa Kernel Oil, Bisabolol, Caprylic/Capric Triglyceride, Carthamus Tinctorius (Safflower) Seed Oil, Coconut Alkanes (And) Coco-Caprylate/Caprates, Helianthus Annuus (Sunflower) Extract, Helianthus Annuus (Sunflower) Seed Oil, Hydrogenated Castor Oil, Oryza Sativa (Rice) Bran Extract, Polyhydroxystearic Acid, Ricinus Communis (Castor) Seed Oil, Rosmarinus Officinalis (Rosemary) Leaf Extract, Sodium Hyaluronate (Hyaluronic Acid), Stearic Acid, Tocopherol, Tocopheryl Acetate (Vitamin E)	
<b>OTHER INFORMATION:</b>	
<ul style="list-style-type: none"> <li>• Protect this product from excessive heat and direct sun</li> </ul>	

MANUFACTURED FOR: Espieve | Costa Mesa, CA 92627 | www.espieve.com

**Net Wt. 6 oz / 170 g**

**PRODUCED BY ESPIEVE  
MADE IN USA**

**TRU SKIN RITUALS SPF 25**

titanium dioxide, zinc oxide spray

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68062-8801
<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	8.16 mg in 170 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	11.56 mg in 170 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>SAFFLOWER OIL</b> (UNII: 65UEH262IS)	
<b>CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE</b> (UNII: FJ1H6M2JG9)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>COCONUT ALKANES</b> (UNII: 1E5KJY107T)	
<b>ARGANIA SPINOSA SEED</b> (UNII: 8H7X7XB54H)	
<b>.BETA.-BISABOLOL</b> (UNII: LP618AV2EA)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68062-8801-1	170 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/17/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	03/17/2023	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Spa de Soleil		874682867	manufacture(68062-8801)

Revised: 3/2023

Spa de Soleil