

NATURAL SPF 30- 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.

Natural SPF 30

Active Ingredients

Titanium Dioxide 7.2%

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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isopropyl palmitate, coconut alkanes, coco caprylate/caprate, caprylic/capric triglyceride, stearic acid, alumina, polyhydroxystearic acid, heptyl undecylenate, oryza sativa (rice) bran extract, rosarinus officnailis (rosemary) extract, helianthus annuus (sunflower) seed oil, 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 30 +

3.3 fl oz | 100 mL

Drug Facts

Active Ingredients / Purpose:

Titanium Dioxide 7.2%.....sunscreen

Uses

■ Provides high protection against sunburn.

Warnings 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.

Directions

■ 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.

Inactive Ingredients:

Isopropyl Palmitate, Coconut Alkanes (And) Coco-Caprylate/Caprate, Caprylic/Capric Triglyceride, Heptyl Undecylenate, Argania Spinosa Kernel Oil, Stearic Acid, *Squalane, Alumina, Oryza Sativa (Rice) Bran Extract, Polyhydroxystearic Acid, Bisabolol, Helianthus Annuus (Sunflower) Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Tocopherol, Tocopheryl Acetate (Vitamin E). * From Sugarcane

NDC # 68062-8304-1 NSC104

MANUFACTURED FOR:

MADE IN USA



NATURAL SPF 30

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68062-8304
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	750 mg in 118 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
JOJOBA OIL (UNII: 724GKU717M)	
SHEA BUTTER (UNII: K49155WL9Y)	
ETHYL MACADAMIATE (UNII: ANA2NCS6V1)	

XANTHAN GUM (UNII: TTV12P4NEE)

SQUALANE (UNII: GW89575KF9)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68062-8304-1	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(68062-8304)

Revised: 12/2022

Spa de Soleil