BOOM SUN SPF 30- titanium dioxide 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.

Boom Sun SPF 30

Active Ingredients

Titanium Dioxide 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 onlyl
- keep out of reach of children

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Directions

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Shake well before use

Using the bulb pipette, dispense 4-6 drops in the palm of the hand.

Rub hands together, then apply liberally and evenly to the face using a circular motion.

Allow 15 minutes after application before sun exposure.

Reapply every 2 hours and after swimming or sweating.

Children under 6 months of age: Ask a doctor.

Protect the product in this container from excessive heat.

Inactive Ingredients

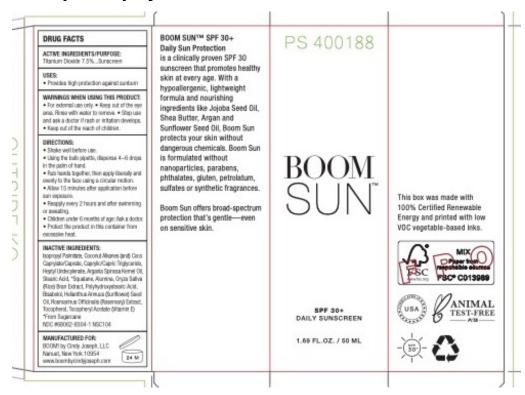
Inactive Ingredients:

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) Seed Oil, Rosmarinus Officinalis (Rosemary) Extract, Tocopherol, Tocopheryl Acetate (Vitamin E)

* From Sugarcane

Principal Display Panel



BOOM SUN SPF 30

titanium dioxide lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68062-9910	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3.75 mg in 50 mL	

Inactive Ingredients			
Ingredient Name	Strength		
TOCOPHEROL (UNII: R0ZB2556P8)			
LEVOMENOL (UNII: 24WE03BX2T)			
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)			
ROSMARINUS OFFICINALIS FLOWERING TOP OIL (UNII: OXN0D3N28L)			
SQUALANE (UNII: GW89575KF9)			

ARGANIA SPINOSA SEED (UNII: 8H7X7XB54H)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
COCONUT ALKANES (UNII: 1E5KJY107T)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
HEPTYL UNDECYLENATE (UNII: W77QUB6GXO)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
ORYZA SATIVA WHOLE (UNII: 84IVV0906Z)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:68062- 9910-1	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/05/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/05/2022	

Labeler - Spa de Soleil (874682867)

Establishment				
Name	Address	ID/FEI	Business Operations	
Spa de Soleil		874682867	manufacture(68062-9910)	

Revised: 12/2022 Spa de Soleil