

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 only
- keep out of reach of children

Keep out of the reach of children.

Directions

Directions

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/Caprates, Caprylic/Capric Triglyceride, Heptyl Undecylenate, Argania Spinosa Kernel Oil, Stearic Acid, *Squalane, Alumina, Oryza Sativa (Rice) Bran Extract, Polyhydroxystearic Acid, Bisabolol, Helianthus

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

* From Sugarcane

Principal Display Panel

DRUG FACTS

ACTIVE INGREDIENTS/PURPOSE:
Titanium Dioxide 7.5%...Sunscreen

USES:
• Provides high protection against sunburn

WARNINGS WHEN USING THIS PRODUCT:
• For external use only. • Keep out of the eye area. Rinse with water to remove. • Stop use and ask a doctor if rash or irritation develops. • Keep out of the reach of children.

DIRECTIONS:
• Shake well before use.
• Using the bulb applicator, dispense 4–6 drops in the palm of hand.
• Rub hands together, then apply liberally and evenly to the face using a circular motion.
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Isopropyl Palmitate, Coconut Alkanes (and) Coco Caprylate/Caprate, Caprylic/Capric Triglyceride, Hexyl Undecylate, Argemone Seed Oil, Stearic Acid, *Squalene, Alanine, Oryza Sativa (Rice) Bran Extract, Polyhydroxybutyrate, Bisabolol, Helianthus Annuus (Sunflower) Seed Oil, Rosmarinus Officinalis (Rosemary) Extract, Tocopherol, Tocopheryl Acetate (Vitamin E)
*From Sugarcane
NDC #68062-6304-1 NDC104

MANUFACTURED FOR:
BOOM! by Cindy Joseph, LLC
Nanuet, New York 10954
www.boombycindyjoseph.com

BOOM SUN™ SPF 30+ Daily Sun Protection
is a clinically proven SPF 30 sunscreen that promotes healthy skin at every age. With a hypoallergenic, lightweight formula and nourishing ingredients like Jojoba Seed Oil, Shea Butter, Argan and Sunflower Seed Oil, Boom Sun protects your skin without dangerous chemicals. Boom Sun is formulated without nanoparticles, parabens, phthalates, gluten, petrolatum, sulfates or synthetic fragrances.

Boom Sun offers broad-spectrum protection that's gentle—even on sensitive skin.

PS 400188

BOOM SUN™

SPF 30+
DAILY SUNSCREEN

1.69 FL. OZ. / 50 ML

This box was made with 100% Certified Renewable Energy and printed with low VOC vegetable-based inks.

FSC MIX Paper from responsible sources FSC® C013988

USA ANIMAL TEST-FREE

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)	

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