BELLA BLUE SKIN CARE TINTED SUNSCREEN- zinc oxide cream BELLA BLU STUDIOS INC

Active Ingredients:

Zinc Oxide 20%

Purpose:

Sunscreen

Uses:

Helps Prevent Sunburn. If used as directed with other sun protection measures (see "Directions"), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings:

For external use only. Do not use on broken or damaged 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.

Warnings:

Keep out of reach of children

Directions:

Apply liberally 15 minutes before sun exposure. Use a water-resistant product if swimming or sweating. Reapply at least every 2 hours. Children under 6 months: Ask a doctor. Sun Protection Measures: 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: Limit time in the sun, especially from 10 a.m. - 2 p.m. Wear long-sleeved shirts, pants, hats and sunglasses.

Inactive Ingredients:

Bismuth Oxychloride, C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogen Dimethicone, Iron Oxides, Mica, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone,

Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

Other Information:

- Protect this product from excessive heat and direct sun
- May stain some fabrics

DRUG FACTS

ACTIVE INGREDIENT:

PURPOSE: Sunscreen

Zinc Oxide 20%

USES:

Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early aging caused by the sun.

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

- · Apply liberally 15 minutes before sun exposure
- · Reapply:
 - · After 40 minutes of swimming or sweating
 - · Immediately after towel drying
 - · At least every 2 hours
- · Children under 6 months: Ask a doctor
- Sun Protection Measures: 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:
 - Limit time in the sun, especially from 10 am- 2 pm
 - · Wear long-sleeved shirts, pants, hats, and sunglasses

INACTIVE INGREDIENTS:

Bismuth Oxychloride, C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG 10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone, Dimethicone, Disodium EDTA, Glycerin, Iron Oxides, Hydrogren Dimethicone, Mica, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylyslilane, Water

OTHER INFORMATION:

- Protect this product from excessive heat and direct sun
- May stain some fabrics

MANUFACTURED FOR:

Bella Blu Studios Inc, Royal Palm Beach, FL 33411 561-360-5555 • www. Bellablustudios.com





Bella Blu Skin Care by Cinthia Shakkour

TINTED SUNSCREEN

Broad Spectrum SPF 40 Water Resistant (40 minutes)

Net Wt. 2.1 oz / 60

BELLA BLUE SKIN CARE TINTED SUNSCREEN

zinc oxide cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:87099-204(NDC:58892-204)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	200 mg in 1 g		

Inactive Ingredients Ingredient Name	Strength
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	Strength
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
BISMUTH OXYCHLORIDE (UNII: 4Z R792I587)	
CI 77491 (UNII: 1K09F3G675)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
CI 77499 (UNII: XM0M87F357)	
CI 77492 (UNII: EX43802MRT)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MICA (UNII: V8A1AW0880)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
TRIETHANOLAMINE (UNII: 903K93S3TK)	
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)	
WATER (UNII: 059QF0KO0R)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
GLYCERIN (UNII: PDC6A3C0OX)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:87099- 204-60	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/15/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/15/2023	

Labeler - BELLA BLU STUDIOS INC (034845239)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis (87099-204)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(87099-204)

Establishment			
Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(87099-204)

Revised: 12/2025 BELLA BLU STUDIOS INC