# BLUEVADO SUNFIX- zinc oxide, titanium dioxide lotion Magic Blue, LLC

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#### **Bluevado Sunfix Sunscreen**

#### **Active Ingredients**

Zinc Oxide 15% Titanium Dioxide 2.8%

#### **Purpose**

Sunscreen

#### Uses

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

#### **Warnings:**

- For external use only
- **Do not use** on damaged or broken skin.
- When using thus product keep out of eyes. Rinse with water to remove.
- Stop use and ask a physicianif rash occurs.

### Keep out of reach of children.

If product is 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
- **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 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 sleeves shirts, pants, hats, and sunglasses
  - Children under 6 months: Ask a physician.

#### Other Information:

Protect this product from excessive heat and direct sun. Provides moderate protection

#### **Inactive Ingredients:**

Ascorbyl Palmitate, Butyrospermum Parkii (Shea) Butter, C13-15 Alkane, Caprylic/Capric Triglyceride, Capryloyl Glycerin/Sebacic Acid Copolymer, Cetearyl Alcohol, Cetyl Alcohol, Citric Acid, Coco-Caprylate, Cocos Nucifera (Coconut) Oil, Glycerin, Glyceryl Isostearate, Glyceryl Stearate, Heptyl Undecylenate, Jojoba Esters, Methylene Blue, Oryza Sativa (Rice) Bran Oil, PEG-100 Stearate, Phenoxyethanol, Polyhydroxystearic Acid, Polysorbate 60, Pongamia Pinnata Seed Extract, Sorbitan Laurate, Water (Aqua), Xanthan Gum.

# Package/Label Principal Display Panel Bluelene®

Bluevado™ SunFix

Protects, Repairs & Moisturizes **SPF 30** 

SPF DAY CREAM

Revolutionary Anti-aging Technology Mineral + Methylene Blue Broad-Spectrum UVA/UVB Coverage

#### **CORAL SAFE**

3 fl oz (90 mL)

Manufactured for Mblue Labs, Bethesda, MD 20817, USA 1-800-988-8068 www.bluelene.com

Label





# SunFix Sunscreen

Protects, Repairs & Moisturizes

Broad Spectrum

SPF 30



### SPF DAY CREAM

Revolutionary Anti-aging Technology Minerals + Methylene Blue Broadspectrum UVA/UVB Coverage

**CORAL SAFE** 

90 ml (3 fl oz)

### **BLUEVADO SUNFIX**

zinc oxide, titanium dioxide lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77358-202	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	15 g in 100 mL	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.8 g in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CITRIC ACID (UNII: 2968PHW8QP)	
HEPTYL UNDECYLENATE (UNII: W77QUB6GXO)	
BUTYROSPERMUM PARKII (SHEA) OIL (UNII: O88E196QRF)	
SORBITAN LAURATE (UNII: 6W9PS8B71J)	
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	
GLYCERYL STEARATE (UNII: 2300U9XXE4)	
COCOS NUCIFERA (COCONUT) OIL (UNII: Q9L0O73W7L)	
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
PONGAMIA PINNATA SEED (UNII: C2BRV53B1V)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
C13-15 ALKANE (UNII: 114P5I43UJ)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLENE BLUE (UNII: T42P99266K)	
RICE BRAN OIL (UNII: LZO6K1506A)	
WATER (UNII: 059QF0KO0R)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CETEARYL ALCOHOL (UNII: 2DMT128M1S)	

Packaging					
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
	1	NDC:77358-202- 03	90 mL in 1 TUBE; Type 0: Not a Combination Product	05/31/2025	

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/31/2025	

## Labeler - Magic Blue, LLC (114903371)

## Registrant - Fragrance Manufacturing, Inc. (793406000)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Fragrance Manufacturing, Inc.		793406000	manufacture(77358-202)	

Revised: 5/2025 Magic Blue, LLC