

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

Bluevado Sunfix Sunscreen

Active Ingredients

Zinc Oxide 8.2%
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 this product** keep out of eyes.
Rinse with water to remove.
- **Stop use and ask a physician** if 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:
 - o Limit time in the sun, especially from 10 a.m. – 2 p.m.
 - o Wear long sleeves shirts, pants, hats, and sunglasses
 - o Children under 6 months: Ask a physician.

Other Information:

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

Inactive Ingredients:

Argania Spinosa (Argan) Kernel Oil, Ascorbyl Palmitate, Bisabolol Butyrospermum Parkii (Shea) Butter, C13-15 Alkane, Caprylic/Capric Triglyceride, Capryloyl Glycerin/Sebacic Acid Copolymer, Cetearyl Alcohol, Cetyl Alcohol, Citrus Aurantium Bergamia (Bergamot) Peel Oil, Citrus Grandis (Grapefruit) Peel Oil, Cocos Nucifera (Coconut) Oil, Glycerin, Glyceryl Stearate, Heptyl Undecylenate, Jojoba Esters, Lavandula Angustifolia (Lavender) Oil, Methylene Blue, Oryza Sativa (Rice) Bran Oil, PEG-100 Stearate, Pelargonium Graveolens (Geranium) Leaf Oil, Phenoxyethanol, Polyhydroxystearic Acid, Polysorbate 60, Sorbitan Laurate, Tocopheryl Acetate, Water (Aqua), Xanthan Gum.

Package/Label Principal Display Panel

Bluelene®

**Bluevado™
SunFix**

Protects, Repairs & Moisturizes

SPF 21

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

Blueelene®

Bluevado™ SunFix

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SPF 21



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3 fl oz (90 mL)

Label

BLUEVADO SUNFIX

zinc oxide, titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77358-201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	8.2 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
ARGAN OIL (UNII: 4V59G5UW9X)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	

LEVOMENOL (UNII: 24WE03BX2T)
SHEA BUTTER (UNII: K49155WL9Y)
C13-15 ALKANE (UNII: 114P5I43UJ)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETYL ALCOHOL (UNII: 936JT6JCN)
BERGAMOT OIL (UNII: 39W1PKE3JI)
CITRUS MAXIMA FRUIT RIND OIL (UNII: 8U3877WD44)
COCONUT OIL (UNII: Q9L0O73W7L)
GLYCERIN (UNII: PDC6A3C0OX)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
HEPTYL UNDECYLENATE (UNII: W77QUB6GXO)
LAVENDER OIL (UNII: ZBP1YXW0H8)
METHYLENE BLUE (UNII: T42P99266K)
RICE BRAN OIL (UNII: LZ06K1506A)
PEG-100 STEARATE (UNII: YD01N1999R)
GERANIUM OIL, ALGERIAN TYPE (UNII: 5Q1I94P4WG)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYSORBATE 60 (UNII: CAL22UVI4M)
SORBITAN MONOLAURATE (UNII: 6W9PS8B71J)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
WATER (UNII: 059QF0KOOR)
XANTHAN GUM (UNII: TTV12P4NEE)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77358-201-03	90 mL in 1 TUBE; Type 0: Not a Combination Product	12/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/01/2021	

Labeler - Magic Blue, LLC (114903371)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing, Inc.		793406000	MANUFACTURE(77358-201)