

BABO BOTANICALS SPF 30 DAILY SHEER TINTED SUNSCREEN - NATURAL GLOW- mineral sunscreen lotion
Babo Botanicals, Inc.

8072 Babo SPF 30 Daily Sheer Tinted

This is a sunscreen manufactured according to the 2009 Final Monograph

The sunscreen is manufactured using only approved mineral active ingredients of Zinc Oxide (6%) and Titanium Oxide (6%) in the preparation of the product (percentage in final product formulation) consistent with The Final Monograph.

Active Ingredient(s)

Zinc Oxide 6% Purpose: Sunscreen

Titanium Dioxide 6% Purpose: Sunscreen

Purpose

Sunscreen

Uses

Uses • Helps prevent sunburn.

Warnings

For external use only.

Do not use

on damaged or broken skin

Keep out of eyes. Rinse with water to remove.

Stop use and ask doctor if rash occurs.

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. Children under 6 months of age: Ask a doctor.

• use a water resistant sunscreen if swimming or sweating • reapply: • immediately after towel drying • at least every 2 hours

Sun Protection Measures

Sun exposure increases risk of skin cancer and early skin aging. To decrease 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 10a.m. - 2p.m. Wear long sleeved shirts, pants, hats and sunglasses.

Inactive ingredients

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice*, Aqua (Deionized Water), Argania Spinosa (Argan) Oil, Beeswax*, Butyrospermum Parkii (Shea) Butter*, C13-14 Alkyls Benzoate, Camellia Sinensis (Green Tea) Extract*, Caryodendron Orinocense (Kahai) Oil, Caprylic/Capric Triglyceride, Cocos Nucifera (Coconut) Oil*, Cucumis Sativus (Cucumber) Extract, Decyl Glucoside, Glycerin*, Glyceryl Caprylate, Glyceryl Stearate Citrate, Glyceryl Stearate, Glyceryl Undecylenate, Helianthus Annuus (Sunflower) Oil*, Hippophae Rhamnoides (Sea Buckthorn) Oil, Hyaluronic Acid, Iron Oxides, Lecithin, Mangifera Indica (Mango) Butter, Punica Granatum (Pomegranate) Extract*, Rosmarinus Officinalis (Rosemary) Oil*, Saccharide Isomerate, Sodium Polyacrylate, Stearic Acid, Tocopherol (Vitamin E), Xanthan Gum, Zemea (Corn) Propanediol.

*Certified Organic ingredients

Package Label - Principal Display Panel

50 mL NDC: 79265-8072-1 Outer packaging



BABO BOTANICALS SPF 30 DAILY SHEER TINTED SUNSCREEN - NATURAL GLOW

mineral sunscreen lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79265-8072
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3000 mg in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3000 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	27.803 mL in 100 mL
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	0.2 mL in 100 mL
ROSEMARY (UNII: IJ67X351P9)	0.05 mL in 100 mL
XANTHAN GUM (UNII: TTV12P4NEE)	0.05 mL in 100 mL
PROPANEDIOL (UNII: 5965N8W85T)	10 mL in 100 mL
YELLOW WAX (UNII: 2ZA36H0S2V)	0.05 mL in 100 mL
SHEA BUTTER (UNII: K49155WL9Y)	1 mL in 100 mL
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	5.5 mL in 100 mL
CARYODENDRON ORINOCENSE WHOLE (UNII: J2T2D81BHU)	0.1 mL in 100 mL
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	5.5 mL in 100 mL
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	1.5 mL in 100 mL
COCONUT OIL (UNII: Q9L0O73W7L)	3 mL in 100 mL
CUCUMBER SEED (UNII: BT3S9L53JK)	0.2 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544)	0.45 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	10 mL in 100 mL
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	8.7 mL in 100 mL
FERRIC OXIDE RED (UNII: 1K09F3G675)	1.547 mL in 100 mL
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	3.5 mL in 100 mL
MANGO (UNII: I629I3NR86)	0.25 mL in 100 mL
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	0.15 mL in 100 mL
STEARIC ACID (UNII: 4ELV7Z65AP)	1 mL in 100 mL
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	0.1 mL in 100 mL
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	0.2 mL in 100 mL
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	0.45 mL in 100 mL
ARGAN OIL (UNII: 4V59G5UW9X)	0.2 mL in 100 mL
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	2 mL in 100 mL
SUNFLOWER OIL (UNII: 3W1JG795YI)	3 mL in 100 mL
HYALURONIC ACID (UNII: S270N0TRQY)	0.1 mL in 100 mL
HIPPOPHAE RHAMNOIDES SEED OIL (UNII: T53SBG6741)	0.2 mL in 100 mL
POMEGRANATE (UNII: 56687D1Z4D)	0.2 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79265-8072-0	1 in 1 BOX	07/24/2020	
1	NDC:79265-8072-1	50 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/24/2020	

