

**BABO BOTANICALS SPF 30 DAILY SHEER TINTED SUNSCREEN - NATURAL GLOW- mineral sunscreen lotion**

**Babo Botanicals, Inc.**

*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.*

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**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

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

### Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	27.803 mL in 100 mL
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	0.2 mL in 100 mL
<b>ROSEMARY</b> (UNII: IJ67X351P9)	0.05 mL in 100 mL
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	0.05 mL in 100 mL
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	10 mL in 100 mL
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	0.05 mL in 100 mL
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	1 mL in 100 mL
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	5.5 mL in 100 mL
<b>CARYODENDRON ORINOCENSE WHOLE</b> (UNII: J2T2D81BHU)	0.1 mL in 100 mL
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	5.5 mL in 100 mL
<b>GLYCERYL STEARATE CITRATE</b> (UNII: WH8T92A065)	1.5 mL in 100 mL
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	3 mL in 100 mL
<b>CUCUMBER SEED</b> (UNII: BT3S9L53JK)	0.2 mL in 100 mL
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	1 mL in 100 mL
<b>GLYCERYL 1-UNDECYLENATE</b> (UNII: B68LJT9544)	0.45 mL in 100 mL
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	10 mL in 100 mL
<b>DECYL GLUCOSIDE</b> (UNII: Z17H97EA6Y)	8.7 mL in 100 mL
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	1.547 mL in 100 mL
<b>LECITHIN, SUNFLOWER</b> (UNII: 834K0WOS5G)	3.5 mL in 100 mL
<b>MANGO</b> (UNII: I629I3NR86)	0.25 mL in 100 mL
<b>SACCHARIDE ISOMERATE</b> (UNII: W8K377W98I)	0.15 mL in 100 mL
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	1 mL in 100 mL
<b>ALPHA-TOCOPHEROL</b> (UNII: H4N855PNZ1)	0.1 mL in 100 mL
<b>SODIUM POLYACRYLATE (8000 MW)</b> (UNII: 285CYO341L)	0.2 mL in 100 mL
<b>GLYCERYL CAPRYLATE</b> (UNII: TM2TZD4G4A)	0.45 mL in 100 mL
<b>ARGAN OIL</b> (UNII: 4V59G5UW9X)	0.2 mL in 100 mL
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	2 mL in 100 mL
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	3 mL in 100 mL
<b>HYALURONIC ACID</b> (UNII: S270N0TRQY)	0.1 mL in 100 mL
<b>HIPPOPHAE RHAMNOIDES SEED OIL</b> (UNII: T53SBG6741)	0.2 mL in 100 mL
<b>POMEGRANATE</b> (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 final	part352	07/24/2020	

