

BABO BOTANICALS DAILY SHEER MINERAL SUNSCREEN SPF 40- zinc oxide, titanium dioxide 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.

Babo Botanicals Daily Sheer Mineral Sunscreen SPF 40

Drug Facts

Active ingredients

Titanium Dioxide 1.9%

Zinc Oxide 15.7%

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 damaged or broken skin.

When using this product

- 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 immediately.

Directions

- Apply liberally to exposed areas 15 minutes before sun exposure.
- Use water resistant sunscreen if swimming or sweating
- Reapply at least every two 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-sleeve shirts, pants, hats and sunglasses.
- **Children under 6 months of age: ask a doctor**

Other information

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

Inactive ingredients

Aloe Barbadensis (Aloe Vera) Leaf Juice, Caprylic/Capric Triglyceride, Calcium Sodium Borosilicate, Cocos Nucifera (Coconut) Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Erythritol, Persea Gratissima (Avocado) Oil, Glyceryl Caprylate, Sodium Stearoyl Glutamate, Cetearyl Alcohol, Rubus Idaeus (Raspberry) Seed Oil, Bisabolol, Helianthus Annuus (Sunflower) Seed Oil, Calendula Officinalis Flower Extract, Chamomilla Recutita (Matricaria) Flower Extract, Nasturtium Officinale (Watercress) Flower/Leaf Extract, Spiraea Ulmaria (Meadowsweet) Flower Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Jojoba Esters, Glycerin, Arachidyl Alcohol, Coco-Glucoside, Behenyl Alcohol, Polyhydroxystearic Acid, Arachidyl Glucoside, Sodium Gluconate, Xanthan Gum, Caprylhydroxamic Acid, Glyceryl Undecylenate, Citric Acid.

Questions and comments?

Call 1-800-422-2987 Mon - Fri

9:00am - 5:00pm EST

Product Packaging



BABO BOTANICALS DAILY SHEER MINERAL SUNSCREEN SPF 40
zinc oxide, titanium dioxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79265-8078
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	157 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	19 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35JOOJ)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
FILIPENDULA ULMARIA FLOWER (UNII: 06L18L32G6)	
ROSEMARY (UNII: IJ67X351P9)	
JOJOBA OIL (UNII: 724GKU717M)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
COCONUT OIL (UNII: Q9L0O73W7L)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
ERYTHRITOL (UNII: RA96B954X6)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
COCO GLUCOSIDE (UNII: ICS790225B)	
LEVOMENOL (UNII: 24WE03BX2T)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GLYCERIN (UNII: PDC6A3C0OX)	
CHAMOMILE (UNII: FGL3685T2X)	
NASTURTIUM OFFICINALE (UNII: YH89GMV676)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79265-8078-1	1 in 1 CARTON	03/01/2023	
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	M020	03/01/2023	

Labeler - Babo Botanicals, Inc. (058258734)

Revised: 4/2023

Babo Botanicals, Inc.