

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

Active Ingredients

Titanium Dioxide 5.9%

Zinc Oxide 3.3%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.

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 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 Juice*, Aluminum Hydroxide, Beeswax*, Butyrospermum Parkii (Shea Butter)*, Camellia Sinensis (Green Tea) Leaf Extract, Cetearyl Alcohol, Coco-Glucoside, Dehydroxanthan Gum, Dicaprylyl Carbonate, Ethylhexylglycerin, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hydrogen Dimethicone, Hydrolyzed Wheat Protein/PVP Crosspolymer, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Methyl Dihydroabietate, Myristyl Alcohol, Myristyl Glucoside, Persea Gratissima (Avocado) Oil, Phenethyl Alcohol, Pongamia Pinnata Seed Oil, Ricinus Communis (Castor) Seed Oil, Rosa Canina Fruit Extract, Simmondsia Chinensis (Jojoba) Seed Oil*, Triethoxycaprylylsilane, Water (Aqua).

*Certified Organic Ingredients

Package Label



BABO BOTANICALS DAILY SHEER MINERAL SUNSCREEN SPF 40

zinc oxide, titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79265-8708
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	33 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	59 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
JOJOBA OIL (UNII: 724GKU717M)	
CASTOR OIL (UNII: D5340Y2I9G)	
ROSA CANINA FRUIT (UNII: 3TNW8D08V3)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DEHYDROXANTHAN GUM (UNII: 63ZP7I1BQO)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
WATER (UNII: 059QF0KO0R)	
SHEA BUTTER (UNII: K49155WL9Y)	
MYRISTYL GLUCOSIDE (UNII: 6AK28695LF)	
KARUM SEED OIL (UNII: 62160PU6FJ)	
COCO GLUCOSIDE (UNII: ICS790225B)	
MYRISTYL ALCOHOL (UNII: V42034O9PU)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
YELLOW WAX (UNII: 2ZA36H0S2V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79265-8708-1	1 in 1 BOX	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)