

**BABO BOTANICALS SUPER SHIELD SPORT SUNSCREEN SPF 50- zinc oxide stick**

**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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**8908 Babo Botanicals Super Shield Sport Stick Sunscreen SPF 50**

**Active Ingredient**

Zinc Oxide (Non-Nano) 19.7%

**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.

**Purpose**

Sunscreen

**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 to exposed areas 15 minutes before sun exposure. **Children under 6 months: ask a doctor.**
- Reapply
- after swimming or sweating

- immediately after towel-drying
- at least every 2 hours
- **Sun Protection Measures:** Spending time increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with a broad-spectrum SPF of 15 or higher and other protection measures including: Limit time in the sun, especially from 10 a.m. - 2 p.m. Wear long sleeves shirts, pants, hats, and sunglasses.

### **Inactive ingredients**

Oryza Sativa (Rice) Bran Oil\*, Persea Gratissima (Avocado) Oil\*, Euphorbia Cerifera (Candelilla) Wax, Octyldodecyl Olivat, Simmondsia Chinensis (Jojoba) Seed Oil\*, Beeswax\*, Theobroma Cacao (Cocoa) Seed Butter\*, Oryzanol, Jojoba Esters, Butyrospermum Parkii (Shea) Butter\*, Calendula Officinalis Flower Extract\*, Chamomilla Recutita (Matricaria) Flower Extract\*, Nasturtium Officinale (Watercress) Flower/Leaf Extract\*, Spiraea Ulmaria (Meadowsweet) Flower Extract\*, Bisabolol\*, Calophyllum Inophyllum (Tamanu) Seed Oil\*, Helianthus Annuus (Sunflower) Seed Oil\*, Tocopherol (Vitamin E).

\*Certified Organic ingredients

### **Other information**

Protect this product from excessive heat and direct sun.

### **Company Information**

Dist. by Babo Botanicals, Inc. 60 East 56th Street

New York, NY 10022

### **Product Packaging**



## BABO BOTANICALS SUPER SHIELD SPORT SUNSCREEN SPF 50

zinc oxide stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79265-8908
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	197 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
<b>NASTURTIUM OFFICINALE</b> (UNII: YH89GMV676)	
<b>FILIPENDULA ULMARIA FLOWER</b> (UNII: 06L18L32G6)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>HYDROGENATED JOJOBA OIL, RANDOMIZED</b> (UNII: Q47ST02F58)	
<b>RICE BRAN OIL</b> (UNII: LZ06K1506A)	
<b>AVOCADO OIL</b> (UNII: 6VNO72PFC1)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>ORYZANOL</b> (UNII: SST9XCL51M)	
<b>CANDELILLA WAX</b> (UNII: WL0328HX19)	
<b>OCTYLDODECYL OLEATE</b> (UNII: MCA43PK7MH)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)	
<b>TAMANU OIL</b> (UNII: JT3LVK84A1)	
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
<b>CHAMOMILE</b> (UNII: FGL3685T2X)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79265-8908-1	1 in 1 BOX	09/01/2022	
1		17 g in 1 CYLINDER; 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	09/01/2022	

**Labeler** - Babo Botanicals, Inc. (058258734)

Revised: 7/2022

Babo Botanicals, Inc.