

**SPF 50 TINTED FACE MINERAL FRAGRANCE FREE SUNSCREEN- mineral
sunscreen 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.

8068 Babo Botanicals SPF 50 Tinted Face Mineral Fragrance Free Sunscreen Stick

79265-8068-0 SPF 50 Tinted Face Mineral Fragrance Free Sunscreen Stick

This product is a mineral sunscreen semi solid stick manufactured pursuant to the sunscreen final monograph.

Primary Container Label

79265-8068-1



DRUG FACTS PANEL

79265-8068-0

Drug Facts

Active Ingredient (Purpose) Zinc Oxide 19.7% (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 a product is swallowed get medical help or contact a Poison Control center right away.

Directions • Apply liberally to exposed areas 15 minutes before sun exposure. Reapply at least every two hours, after 80 minutes of swimming or sweating, or immediately after towel-drying.

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 protection measures including: Limit time in the sun, especially from 10 a.m. – 2 p.m. and wear long-sleeve shirts, pants, hats, and sunglasses. **Children under 6 months: Ask a doctor**

Inactive Ingredients: ARGANIA SPINOSA KERNEL EXTRACT, BEESWAX*, BISABOLOL*, BUTYROSPERMIUM PARKII (SHEA) BUTTER*, CALENDULA OFFICINALIS FLOWER EXTRACT*, CALOPHYLLUM INOPHYLLUM SEED OIL*, CHAMOMILLA RECUTITA (MATRICARIA) FLOWER EXTRACT*, COFFEA ARABICA (COFFEE) SEED EXTRACT, EUPHORBIA CERIFERA (CANDLELLA) WAX, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL*, HIPPOPHAE RHAMNOIDES FRUIT EXTRACT, IRON OXIDES, JOJOBA ESTERS, NASTURTIUM OFFICINALE FLOWER/LEAF EXTRACT*, OCTYLDODECANOL, OCTYLDODECYL OLEATE, ORYZANOL, ORYZA SATIVA (RICE) BRAN OIL*, PERSEA GRATISSIMA (AVOCADO) OIL*, PUEBARIA LOBATA ROOT EXTRACT*, ROSA CANINA FRUIT EXTRACT, SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL*, SPIRAEA LUMARIA FLOWER EXTRACT*, THEOBROMA CACAO (COCOA) SEED BUTTER*, TOCOPHEROL, TRIHYDROXYSTEARIN.

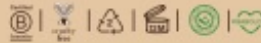
Other Information • Protect this product from excessive heat and direct sun.

Questions and comments: Call 1-877-537-BABO

*Certified Organic Ingredients

Dist. by Babo Botanicals, Inc.
14 Harwood Court, Scarsdale, NY 10583
1.877.537.BABO www.babobotanicals.com

MADE IN THE USA
with US & imported materials.



ACTIVE INGREDIENTS

Zinc Oxide 20.2115%

USES

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

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DO NOT USE

Do not use on damaged or broken skin

WHEN USING THIS PRODUCT

When using this product Keep out of eyes. Rinse with water to remove

STOP USE AND ASK A DOCTOR

Stop use and ask doctor if rash occurs

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. If a product is swallowed get medical help or contact a Poison Control center right away.

DIRECTIONS

DIRECTIONS Apply liberally to exposed areas 15 minutes before sun exposure. Reapply at least every two hours, after 80 minutes of swimming or sweating, or immediately after towel-drying

INACTIVE INGREDIENTS

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*CERTIFIED ORGANIC INGREDIENT

OTHER INFORMATION

Protect this product from excessive heat and direct sun.

QUESTIONS / COMMENTS?

Questions and comments: Call 1-877-537-BABO

INFORMATION PANEL

79265-8068-0 INFORMATION PANEL

A tinted, mineral sunscreen that adds powerful broad-spectrum UVA/UVB protection while delivering a hint of tint for a gorgeous, glowing finish. Enriched with certified organic ingredients, this pocket sized sunscreen can be used under (or instead of) foundation for smoother, brighter-looking skin. When worn alone, creates a nice dewey glow with light tint coverage. The sheer, anti-oxidant rich formula hydrates skin while diminishing the appearance of dullness and enlarged pores.



No Icky Chemicals

Hypoallergenic

Preservative Free

Dairy, Soy & Gluten Free

Paraben & Phthalate Free

No Added Fragrance

Principal Display Panel

0.6 oz. 17 g 79265-8068-0



SPF 50 TINTED FACE MINERAL FRAGRANCE FREE SUNSCREEN

mineral sunscreen stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79265-8068
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20.2115 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE RED (UNII: 1K09F3G675)	0.5362 mL in 100 g
PUERARIA MONTANA VAR. LOBATA ROOT (UNII: PET93F4I3C)	0.0015 mL in 100 g
FILIPENDULA ULMARIA FLOWER (UNII: 06L18L32G6)	0.0015 mL in 100 g
HIPPOPHAE RHAMNOIDES FRUIT (UNII: AVL0R9111T)	0.00125 mL in 100 g
SUNFLOWER OIL (UNII: 3W1JG795YI)	0.1875 mL in 100 g
TRIHYDROXYSTEARIN (UNII: 06YD7896S3)	0.0092 mL in 100 g
HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58)	0.9023 mL in 100 g
NASTURTIUM OFFICINALE FLOWERING TOP (UNII: W1N2U8I64G)	0.0015 mL in 100 g
ROSA CANINA FRUIT (UNII: 3TNW8D08V3)	0.00125 mL in 100 g
JOJOBA OIL (UNII: 724GKU717M)	7.5 mL in 100 g
COCOA BUTTER (UNII: 512OYT1CRR)	3 mL in 100 g
ARGANIA SPINOSA SEED (UNII: 8H7X7XB54H)	0.00125 mL in 100 g
TOCOPHEROL (UNII: R0ZB2556P8)	0.75 mL in 100 g
AVOCADO OIL (UNII: 6VNO72PFC1)	15 mL in 100 g
RICE BRAN OIL (UNII: LZ06K1506A)	23.07 mL in 100 g
CANDELILLA WAX (UNII: WL0328HX19)	9.5 mL in 100 g
ARABICA COFFEE BEAN (UNII: 3SW678MX72)	0.00125 mL in 100 g
OCTYLDODECYL OLEATE (UNII: MCA43PK7MH)	8.75 mL in 100 g
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	0.0015 mL in 100 g
SHEA BUTTER (UNII: K49155WL9Y)	1 mL in 100 g
CALOPHYLLUM TACAMAHACA SEED OIL (UNII: 05G85L61OE)	0.01 mL in 100 g
CHAMOMILE (UNII: FGL3685T2X)	0.0015 mL in 100 g
WHITE WAX (UNII: 7G1J5DA97F)	6 mL in 100 g
LEVOMENOL (UNII: 24WE03BX2T)	0.2 mL in 100 g
OCTYLDODECANOL (UNII: 461N1O614Y)	0.3608 mL in 100 g
ORYZANOL (UNII: SST9XCL51M)	3 mL in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79265-8068-0	1 in 1 BOX	11/01/2020	
1	NDC:79265-8068-1	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	part352	11/01/2020	

Labeler - Babo Botanicals, Inc. (058258734)

Registrant - Bell International Laboratories (967781555)

Establishment

Name	Address	ID/FEI	Business Operations
Bell International Laboratories		967781555	manufacture(79265-8068)

Revised: 10/2021

Babo Botanicals, Inc.