

**BABO BOTANICALS SWIM AND SPORT MINERAL SUNSCREEN BALM SPF 50-  
zinc oxide salve**

**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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**Babo Botanicals Swim and Sport Mineral Sunscreen Balm SPF 50**

**Drug Facts**

**Active ingredient**

Zinc Oxide 24.5%

**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 15 minutes before sun exposure.
- Reapply after 80 minutes of swimming or sweating, immediately after towel-drying, 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**

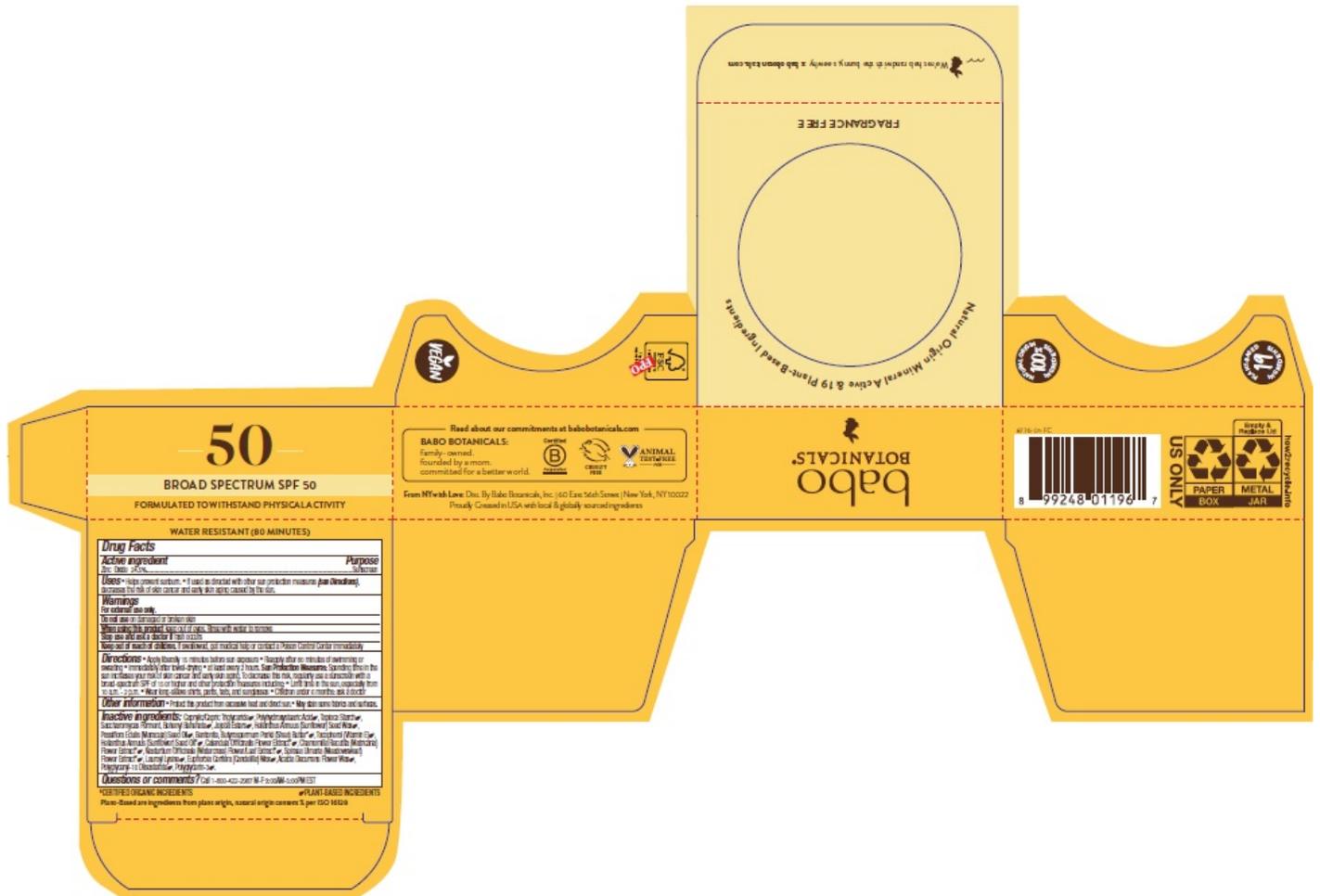
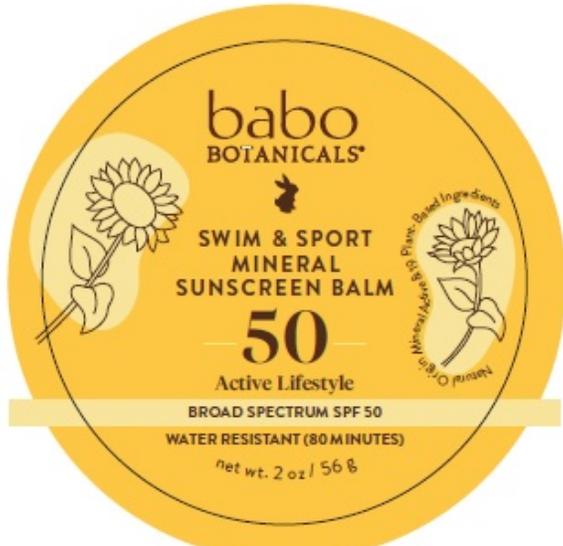
Caprylic/Capric Triglyceride, Polyhydroxystearic Acid, Tapioca Starch, Saccharomyces Ferment, Behenyl Behenate, Jojoba Esters, Helianthus Annuus (Sunflower) Seed Wax, Passiflora Edulis (Maracuja) Seed Oil, Bentonite, Butyrospermum Parkii (Shea) Butter, Tocopherol (Vitamin E), Helianthus Annuus (Sunflower) Seed Oil, Calendula Officinalis Flower Extract, Chamomilla Recutita (Matricaria) Flower Extract, Nasturtium Officinale (Watercress) Flower/Leaf Extract, Spiraea Ulmaria (Meadowsweet) Flower Extract, Lauroyl Lysine, Euphorbia Cerifera (Candelilla) Wax, Acacia Decurrens Flower Wax, Polyglyceryl-10 Diisostearate, Polyglycerin-3.

#### **Questions or comments?**

Call 1-800-422-2987 M-F

9:00am - 5:00pm EST

#### **Product Packaging**



# BABO BOTANICALS SWIM AND SPORT MINERAL SUNSCREEN BALM SPF 50

zinc oxide salve

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79265-8776
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	245 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
BENTONITE (UNII: A3N5ZCN45C)	
SHEA BUTTER (UNII: K49155WL9Y)	
LAUROYL LYSINE (UNII: 113171Q70B)	
FILIPENDULA ULMARIA FLOWER (UNII: 06L18L32G6)	
PASSIFLORA EDULIS SEED OIL (UNII: F3VOA31UHQ)	
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZ E9IY9)	
BEHENYL BEHENATE (UNII: K8NU647RJ0)	
CANDELILLA WAX (UNII: VL0328HX19)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	
TOCOPHEROL (UNII: R0ZB2556P8)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CHAMOMILE (UNII: FGL3685T2X)	
NASTURTIUM OFFICINALE (UNII: YH89GMV676)	
STARCH, TAPIOCA (UNII: 24SC3U704I)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79265-8776-1	1 in 1 CARTON	04/02/2023	
1		56 g in 1 CAN; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	M020	04/02/2023	

Revised: 4/2023

Babo Botanicals, Inc.