BABO BOTANICALS SWIM AND SPORT MINERAL SUNSCREEN SPF 30- zinc oxide spray 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 Swim and Sport Mineral Sunscreen Spray SPF 30

Drug Facts

Active ingredient

Zinc Oxide 14.5%

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

- Shake well
- 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

Water (Aqua), Helianthus Annuus (Sunflower) Seed Oil, Butyloctyl Salicylate, Tetradecane, Caprylic/Capric Triglyceride, Carthamus Tinctorius (Safflower) Seed Oil, Methyl Dihydroabietate, Bentonite, Cetearyl Alcohol, Propanediol, Passiflora Edulis (Maracuja) Seed Oil, Jojoba Esters, Tocopherol (Vitamin E), Glycerin, Bisabolol, Calendula Officinalis Flower Extract, Chamomilla Recutita (Matricaria) Flower Extract, Nasturtium Officinale (Watercress) Flower/Leaf Extract, Spiraea Ulmaria (Meadowsweet) Flower Extract, Microcrystalline Cellulose, Coco-Glucoside, Polyhydroxystearic Acid, Caprylhydroxamic Acid, Cellulose Gum, Caprylyl Glycol.

Questions or comments?

Call 1-800-422-2987 M-F

9:00am - 5:00pm EST

Product Packaging



BABO BOTANICALS SWIM AND SPORT MINERAL SUNSCREEN SPF 30

zinc oxide spray

Product Information							
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:792	NDC:79265-8775		
Route of Administration	TOPICAL						
Active Ingredient/Active Moiety							
Ingredient Name			Basis of Streng	th S	Strength		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)			ZINC OXIDE	145	mg in 1 mL		
Inactive Ingredients							
Ingredient Name					Strength		
CAPRYLYL GLYCOL (UNII: 00YIU54	38U)						

POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
BENTONITE (UNII: A3N5ZCN45C)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
FILIPENDULA ULMARIA FLOWER (UNII: 06L18L32G6)	
PASSIFLORA EDULIS SEED OIL (UNII: F3VOA31UHQ)	
JOJOBA OIL (UNII: 724GKU717M)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
PROPANEDIOL (UNII: 5965N8W85T)	
TETRADECANE (UNII: 03LY784Y58)	
WATER (UNII: 059QF0K00R)	
TOCOPHEROL (UNII: R0ZB2556P8)	
COCO GLUCOSIDE (UNII: ICS790225B)	
LEVOMENOL (UNII: 24WE03BX2T)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GLYCERIN (UNII: PDC6A3C0OX)	
CHAMOMILE (UNII: FGL3685T2X)	
NASTURTIUM OFFICINALE (UNII: YH89GMV676)	
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
Packaging	
rackaying	

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1		177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/02/2023	

Marketing Information

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

Labeler - Babo Botanicals, Inc. (058258734)

Revised: 4/2023

Babo Botanicals, Inc.