# BABO BABY SKIN MINERAL SUNSCREEN FF- mineral sunscreen spray Babo Botanicals, Inc.

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8579 Babo SPF 30 Baby Skin Mineral Non-Aerosol Sunscreen Pump Spray, FF

### SPF 30 Baby Skin Mineral Non-Aerosol Sunscreen Pump Spray, FF

This product is an OTC sunscreen manufactured according to the Sunscreen Final Rule. Active ingredient: Zinc Oxide

# **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

### **Purpose**

Sunscreen

## **Warnings**

For external use only.

#### Do not use

on damaged or broken skin.

# When using this product

Keep out of eye. 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. 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**

**BENTONITE** 

**BISABOLOL\*** 

**BUTYLOCTYL SALICYLATE** 

CALENDULA OFFICINALIS FLOWER EXTRACT\*

CAPRYLHYDROXAMIC ACID

CAPRYLIC/CAPRIC TRIGLYCERIDE

CAPRYLYL GLYCOL

CARTHAMUS TINCTORIUS (SAFFLOWER) SEED OIL

**CELLULOSE GUM** 

CETEARYL ALCOHOL

CHAMOMILLA RECUTITA (MATRICARIA) FLOWER EXTRACT\*

COCO GLUCOSIDE

**GLYCERIN\*** 

HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL\*

**JOJOBA ESTERS** 

METHYL DIHYDROABIETATE

MICROCRYSTALLINE CELLULOSE

NASTURTIUM OFFICINALE (WATERCRESS) FLOWER/LEAF EXTRACT\*

POLYHYDROXYSTEARIC ACID

**PROPANEDIOL** 

PUERARIA LOBATA (KUDZU) ROOT EXTRACT\*

SPIRAEA ULMARIA (MEADOWSWEET) FLOWER EXTRACT\*

**TETRADECANE** 

TOCOPHEROL

WATER (AQUA)

#### Other information

Protect this product from excessive heat and direct sun. May stain some fabrics. You may report a serious adverse event to the phone number or address provided below.

### **Questions and comments**

Call toll free 1-877-537-BABO Monday-Friday 9:00 am - 5:00 EST

79265-8579-6 6 fl. oz. / 177 mL

new BOTANICALS

# BABY SKIN

MINERAL SUNSCREEN SPRAY

Non-Aerosol



**Broad Spectrum Sunscreen SPF 30** 100% Zinc Oxide Active Ingredient Water Resistant (80 Minutes) Non-Greasy & Lightweight



FRAGRANCE FREE

6 fl oz / 177 ml

#### For Sensitive Skin @ Face & Body 100% Non-Nano Zinc Oxide Active Ingredient, Vegan. Gluten, Soy And Dairy Free. Rich in Anti-Oxidants.

#### 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 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. • Wear long-sleeve shirts, pants, hats, and sunglasses. • Children under 6 months: ask a doctor

Inactive Ingredients: BENTONTE, BISABOLOL\*, BUTYLOCTYL SALICYLATE, CALENDULA OFFICINALIS FLOWER EXTRACT\*, CAPRYLHYDROXAMIC ACID, CAPRYLIC/CAPRIC TRIGLYCERIDE, CAPRYLYL GLYCOL, CARTHAMUS TINCTORIUS (SAFFLOWER) SEED OIL, CELLULOSE GUM, CETEARYL ALCOHOL, CHAMOMILLA RECUTITA (MATRICARIA) FLOWER EXTRACT\*, COCO-GLUCOSIDE, GLYCERIN\*, HELIANTHUS ANNUUS (SUNFLOWER) OIL\*, JOJOBA ESTERS, METHYL DIHYDROABETATE, MICROCRYSTALLINE CELLULOSE, NASTURTIUM OFFICINALE FLOWERLEAF EXTRACT\*, POLYHYDROXYSTEARIC ACID, PROPANEDIOL, PUERARIA LOBATA ROOT EXTRACT\*, SPIRAEA ULMARIA FLOWER EXTRACT\*, TETRADECANE, TOCOPHEROL, WATER (AQUA). \*Certified Organic Ingredients

Other Information • Protect this product from excessive heat and direct sun. May stain some fabrics. You may report a serious adverse event to the phone number or address provided below.

#### Questions or comments?

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14 Harwood Court Scarsdale, NY 10583 1.877.537.BABO

www.babobotanicals.com

# **BABO BABY SKIN MINERAL SUNSCREEN FF**

mineral sunscreen spray

#### **Product Information**

HUMAN OTC DRUG NDC:79265-8579 **Product Type** Item Code (Source)

**Route of Administration TOPICAL** 

# **Active Ingredient/Active Moiety**

**Ingredient Name Basis of Strength** Strength ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) ZINC OXIDE 14.5 g in 100 mL

## **Inactive Ingredients**

Ingredient Name	Strength
PUERARIA MONTANA VAR. LOBATA ROOT (UNII: PET93F4I3C)	0.00015 mL in 100 mL
TETRADECANE (UNII: 031Y784Y58)	5 ml in 100 ml

WATER (UNII: 059QF0KO0R)	53.8608 mL in 100 mL
BENTONITE (UNII: A3N5ZCN45C)	1.5 mL in 100 mL
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	0.7 mL in 100 mL
LEVOMENOL (UNII: 24WE03BX2T)	0.3 mL in 100 mL
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	1.105 mL in 100 mL
CHAMOMILE (UNII: FGL3685T2X)	0.00015 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.15845 mL in 100 mL
SUNFLOWER OIL (UNII: 3W1JG795YI)	6 mL in 100 mL
HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58)	0.38 mL in 100 mL
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	2 mL in 100 mL
PROPANEDIOL (UNII: 5965N8W85T)	1 mL in 100 mL
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)	0.09 mL in 100 mL
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	5 mL in 100 mL
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	0.00015 mL in 100 mL
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	0.15 mL in 100 mL
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	3 mL in 100 mL
SAFFLOWER OIL (UNII: 65UEH262IS)	3 mL in 100 mL
COCO GLUCOSIDE (UNII: ICS790225B)	0.595 mL in 100 mL
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	0.66 mL in 100 mL
NASTURTIUM OFFICINALE FLOWERING TOP (UNII: W1N2U8I64G)	0.00015 mL in 100 mL
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	0.25 mL in 100 mL
FILIPENDULA ULMARIA FLOWER (UNII: 06L18L32G6)	0.00015 mL in 100 mL
TOCOPHEROL (UNII: R0ZB2556P8)	0.75 mL in 100 mL

Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:79265- 8579-6	177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/01/2020	

Marketing In	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M020	11/01/2020	12/31/2024	

# Labeler - Babo Botanicals, Inc. (058258734)

Revised: 12/2024 Babo Botanicals, Inc.