

BABY SKIN MINERAL SUNSCREEN- mineral sunscreen lotion
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.

8578 SPF 50 Baby Skin Mineral Sunscreen Lotion

This is a sunscreen with the approved active ingredient of Zinc Oxide at 20%.

Active Ingredient(s)

Zinc Oxide 20%. Purpose: Sunscreen

Purpose

Sunscre

Use

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.

Other information

Protect this product from excessive heat and direct sun

Inactive ingredients

ARACHIDYL ALCOHOL, ARACHIDYL GLUCOSIDE, BEHENYL ALCOHOL, BISABOLOL*, BUTYLOCTYL SALICYLATE, BUTYROSPERMUM PARKII (SHEA BUTTER), CALENDULA OFFICINALIS FLOWER EXTRACT*, CAPRYLHYDROXAMIC ACID, CAPRYLYL GLYCOL,

CARTHAMUS TINCTORIUS (SAFFLOWER) SEED OIL, CELLULOSE GUM, CETEARYL ALCOHOL, CETYL ALCOHOL, CHAMOMILLA RECUTITA (MATRICARIA) FLOWER EXTRACT*, CITRIC ACID, COCO-GLUCOSIDE, COCOS NUCIFERA (COCONUT) OIL, GLYCERIN, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, METHYL DIHYDROABIETATE, MICROCRYSTAL-LINE CELLULOSE, NASTURTIUM OFFICINALE FLOWER/LEAF EXTRACT*, POLYHYDROXYSTEARIC ACID, PUERARIA LOBATA ROOT EXTRACT*, SODIUM GLUCONATE, SODIUM HYALURONATE, SODIUM STEAROYL GLUTAMATE, SPIRAEA ULMARIA FLOWER EXTRACT*, THEOBROMA CACAO (COCOA) SEED BUTTER*, TOCOPHEROL, WATER (AQUA). *Certified Organic Ingredients

Package Label - Principal Display Panel

3 fl oz / 89 mL ml NDC: 79265-8578-3

BABO BOTANICALS
Babo Skin Mineral Sunscreen
SKU 8578-01
RELEASED TBD



126,900 (Total width)
63,450 (Inner width)
115,000 (Total height)
100,500 (Inner height)
3,000 (Bottom margin)

5,000 (Left margin)
39,725 (Text area width)
31,725 (Image area width)
31,725 (Text area width)
23,725 (Image area width)
5,000 (Right margin)

1,500 (Text area height)
7,500 (Image area height)
4,000 (Text area height)
2,000 (Image area height)
6,000 (Text area height)

BEEF FRIENDLY (Logo)

babo BOTANICALS®

BABY SKIN MINERAL SUNSCREEN

Sheer & Gentle Lotion

SPF 50

100% Zinc as Active Ingredient
Water Resistant (80 Minutes)
Broad Spectrum Sunscreen
Ultra Sheer & Lightweight

FRAGRANCE FREE

3 fl oz / 89 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	Purpose
Zinc Oxide 20%	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 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: ARACHIDYL ALCOHOL, ARACHIDYL GLUCOSIDE, BEHENYL ALCOHOL, BISABOLOL, BUTYLOCTYL SALICYLATE, BUTYROSPERMUM PARKII (SHEA BUTTER), CALENDULA OFFICINALIS FLOWER EXTRACT*, CAPRYLHYDROXYAMIC ACID, CAPRYLYL GLYCOL, CARTHAGUS TINCTORIUS CAYENNE SEED OIL, CELLULOSE GUM, CETEARYL ALCOHOL, CETYL ALCOHOL, CHAMOMILLA RECUTITA (MATRICARIA) FLOWER EXTRACT*, CITRIC ACID, COCO-GLUCOSIDE, COCOS NUCIFERA (COCONUT) OIL, GLYCERIN, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, METHYL DIBROMOGLUCATE, MICROCRYSTALLINE CELLULOSE, NASTURTIUM OFFICINALE FLOWER/LEAF EXTRACT*, POLYHYDROXYSTEARIC ACID, PUERARIA LOBATA ROOT EXTRACT*, SODIUM GLUCONATE, SODIUM HYALURONATE, SODIUM STEAROYL GLUTAMATE, SPIRAEA ULMARIA FLOWER EXTRACT*, THEOBROMA CACAO (COCOA) SEED BUTTER, TOCOPHEROL, WATER (AQUA).

***Certified Organic Ingredients**

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

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

Dist. by Babo Botanicals, Inc.
14 Riverside Court, Scarsdale, NY 10583
1.877.537.BABO www.babobotanicals.com
MADE IN THE USA with US & imported materials.

8 69248 01071 7

ECO-FRIENDLY
100% RECYCLED PAPER
NO GLUE
NO PLASTIC

AQUA BACKGROUND PRINTS 80% PMS 318

PINK ACCENTS PRINT 100% PMS 706

UPC PRINTS BLACK

- Bleed**
- Printing area (text, logos, ...)**
- Free text printing area**

mineral sunscreen lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79265-8578
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 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	0.0001 mL in 100 mL
PUERARIA MONTANA VAR. LOBATA ROOT (UNII: PET93F4I3C)	0.0001 mL in 100 mL
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	1.3 mL in 100 mL
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	0.2 mL in 100 mL
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	1.3 mL in 100 mL
TOCOPHEROL (UNII: ROZB2556P8)	0.75 mL in 100 mL
LEVOMENOL (UNII: 24WE03BX2T)	0.3 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.15 mL in 100 mL
WATER (UNII: 059QF0KO0R)	46.0495 mL in 100 mL
NASTURTIUM OFFICINALE FLOWERING TOP (UNII: W1N2U8I64G)	0.0001 mL in 100 mL
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	0.25 mL in 100 mL
SODIUM GLUCONATE (UNII: R6Q3791S76)	0.2 mL in 100 mL
CETYL ALCOHOL (UNII: 936JST6JCN)	0.75 mL in 100 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.2 mL in 100 mL
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	0.7 mL in 100 mL
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	0.144 mL in 100 mL
CHAMOMILE (UNII: FGL3685T2X)	0.0001 mL in 100 mL
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	5 mL in 100 mL
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	0.972 mL in 100 mL
ARACHIDYL GLUCOSIDE (UNII: 6JVV35JOOJ)	0.324 mL in 100 mL
DOCOSANOL (UNII: 9G1OE216XY)	0.504 mL in 100 mL
SHEA BUTTER (UNII: K49155WL9Y)	2.1 mL in 100 mL
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	0.15 mL in 100 mL
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	3 mL in 100 mL
COCO GLUCOSIDE (UNII: ICS790225B)	0.7 mL in 100 mL
COCONUT OIL (UNII: Q9L0O73W7L)	5 mL in 100 mL
SUNFLOWER OIL (UNII: 3W1JG795YI)	5.1 mL in 100 mL
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	1.056 mL in 100 mL
FILIPENDULA ULMARIA FLOWER (UNII: 06L18L32G6)	0.0001 mL in 100 mL
COCOA BUTTER (UNII: 512OYT1CRR)	0.8 mL in 100 mL
SAFFLOWER OIL (UNII: 65UEH262IS)	3 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79265-8578-3	89 mL in 1 TUBE; Type 0: Not a Combination Product	08/26/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/26/2020	

Labeler - Babo Botanicals, Inc. (058258734)

Registrant - Bell International Laboratories (967781555)

Establishment

Name	Address	ID/FEI	Business Operations
Bell International Laboratories		967781555	manufacture(79265-8578)

Revised: 10/2021

Babo Botanicals, Inc.