

BABY MINERAL SUNSCREEN SPF55- zinc oxide lotion
Hello Bello

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.

Baby Mineral Sunscreen SPF55+

Drug Facts

Active Ingredients

Zinc Oxide 20.0%

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

broken or damaged skin

When using this product

Keep out of eyes. Rinse with water to remove

Stop use and ask a doctor if

rash occurs

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- Shake well before use
- Apply liberally and spread evenly by hand 15 minutes before sun exposure

- Reapply after 80 minutes of swimming or sweating, immediately after towel use, at least every 2 hours
- For children under 6 months of age, ask a doctor
- **Sun Protection Measures** Spending time in the sun can increase your risk of skin cancer and early skin aging. To decrease this risk, regularly use sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - Limiting time in the sun, especially from 10a.m. - 2p.m.
 - Wearing long-sleeved shirts, pants, hats and sunglasses

Other Information

- Protect this product from excessive heat and direct sun
- Avoid long-term exposure storage above 40°C (104°F)
- May stain some fabrics

Inactive Ingredients

Arachidyl Alcohol, Arachidyl Glucoside, Behenyl Alcohol, Bisabolol*, Butyloctyl Salicylate, Butyrospermum Parkii (Shea) Butter*, Calendula Officinalis Flower Extract*, Camellia Sinensis Leaf Extract*, Caprylhydroxamic Acid, Capryloyl Glycerin/Sebacic Acid Copolymer, Caprylyl Glycol, Cellulose Gum, Cetearyl Alcohol, Cetyl Alcohol, Chamomilla Recutita (Matricaria) Flower Extract*, Citric Acid, Citrus Aurantium Dulcis (Orange) Peel Oil, Coco Glucoside, Cocos Nucifera (Coconut) Oil*, Cucumis Sativus (Cucumber) Fruit Extract*, Diheptyl Succinate, Glycerin, Methyl Dihydroabietate, Microcrystalline Cellulose, Persea Gratissima (Avocado) Fruit Extract*, Polyhydroxystearic Acid, Prunus Armeniaca (Apricot) Kernel Oil*, Sodium Gluconate, Sodium Hyaluronate, Sodium Stearoyl Glutamate, Theobroma Cacao (Cocoa) Seed Butter, Tocopherol, Triethyl Citrate, Vanilla Planifolia Fruit Extract, Water (Aqua) *Organic

- Dermatologist-Tested • Non-Greasy
- Hypoallergenic

Cover up and have some fun in the sun knowing our non-nano Mineral Sunscreen is helping protect and nourish your family's skin.

ACTIVE INGREDIENTS	PURPOSE
Zinc Oxide – 20.0%	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	
WARNING: 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 a 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 15 minutes before sun exposure • Reapply: After 80 minutes of swimming or sweating + immediately after towel drying • At least every 2 hours • For children under 6 months of age: ask a doctor	
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 value of 15 or higher and other sun protection measures including: limited time in the sun, especially from 10 a.m. - 2 p.m. Wear long-sleeved shirts, pants, hats, and sunglasses.	
INACTIVE INGREDIENTS: Arachidyl Alcohol, Arachidyl Glucoside, Behenyl Alcohol, Bisabolol, Butyloctyl Salicylate, Butyrospermum Parkii (Shea) Butter, Calendula Officinalis Flower Extract, Camellia Sinensis Leaf Extract, Caprylhydroxamic Acid, Capryloyl Glycerin/Sebacic Acid Copolymer, Caprylyl Glycol, Cellulose Gum, Cetearyl Alcohol, Cetyl Alcohol, Chamomilla Recutita (Matricaria) Flower Extract, Citric Acid, Citrus Aurantium Dulcis (Orange) Peel Oil, Coco-Glucoside, Cocos Nucifera (Coconut) Oil, Cucumis Sativus (Cucumber) Fruit Extract, Diheptyl Succinate, Glycerin, Methyl Dihydroabietate, Microcrystalline Cellulose, Polyhydroxystearic Acid, Persea Gratissima (Avocado) Fruit Extract, Prunus Armeniaca (Apricot) Kernel Oil, Sodium Gluconate, Sodium Hyaluronate, Sodium Stearoyl Glutamate, Theobroma Cacao (Cocoa) Seed Butter, Tocopherol, Triethyl Citrate, Vanilla Planifolia Fruit Extract, Water (Aqua) – Organic	

Baby
Mineral
Sunscreen



Made in the US with US and imported materials? Yep.
Questions? (888) 860-6888
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Hello Bello, Los Angeles, CA 90272



- Reef-Friendly
- Water-Resistant (80 Minutes)
- NET WT. 3.0 fl. oz. (88.7 ml) e

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BABY MINERAL SUNSCREEN SPF55
zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73418-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
LEVOMENOL (UNII: 24WE03BX2T)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHAMOMILE (UNII: FGL3685T2X)	
ORANGE OIL (UNII: AKN3KSD11B)	
DIHEPTYL SUCCINATE (UNII: 057N7SS26Y)	
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	
APRICOT KERNEL OIL (UNII: 54JB35T06A)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
TOCOPHEROL (UNII: R0ZB2556P8)	
VANILLA BEAN (UNII: Q74T35078H)	
WATER (UNII: 059QF0KO0R)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
DOCOSANOL (UNII: 9G1OE216XY)	
COCOA BUTTER (UNII: 512OYT1CRR)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35JOOJ)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCO GLUCOSIDE (UNII: ICS790225B)	
COCONUT OIL (UNII: Q9L0O73W7L)	
CUCUMBER (UNII: YY7C30VXJT)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
AVOCADO (UNII: SDS87L369F)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
SHEA BUTTER (UNII: K49155WL9Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73418-100-03	85.05 g in 1 TUBE; Type 0: Not a Combination Product	07/28/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	07/28/2023	

Labeler - Hello Bello (081135707)

Revised: 7/2023

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