# MINERAL SUNSCREEN SPF 50- 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.

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#### Mineral Sunscreen Lotion SPF50

### **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

- after 80 minutes of swimming or sweating immediately after towel use
- at least every 2 hours

Reapply:

#### **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

Children under six months: Ask a doctor

#### 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 (Green Tea) 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

#### Questions?

(888)860-6888



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### **MINERAL SUNSCREEN SPF 50**

zinc oxide lotion

#### **Product Information**

HUMAN OTC DRUG NDC:73418-102 **Product Type** Item Code (Source)

TOPICAL **Route of Administration** 

### **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		
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)			
ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ)			
DOCOSANOL (UNII: 9G10E216XY)			
LEVOMENOL (UNII: 24WE03BX2T)			

BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SHEA BUTTER (UNII: K49155WL9Y)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHAMOMILE (UNII: FGL3685T2X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ORANGE OIL (UNII: AKN3KSD11B)	
COCO GLUCOSIDE (UNII: ICS790225B)	
COCONUT OIL (UNII: Q9L0O73W7L)	
CUCUMBER (UNII: YY7C30VXJT)	
DIHEPTYL SUCCINATE (UNII: 057N7SS26Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
AVOCADO (UNII: SDS87L369F)	
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	
APRICOT KERNEL OIL (UNII: 54JB35T06A)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
COCOA BUTTER (UNII: 5120YT1CRR)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
VANILLA BEAN (UNII: Q74T35078H)	
WATER (UNII: 059QF0KO0R)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:73418-102- 05	141.75 g in 1 TUBE; Type 0: Not a Combination Product	07/31/2023	

Marketing In	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	M020	07/30/2023		

## Labeler - Hello Bello (081135707)

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