

## **MINERAL SUNSCREEN SPF30- zinc oxide spray**

**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 Spray SPF30**

#### ***Drug Facts***

#### ***Active Ingredients***

Zinc Oxide 14.0%

#### ***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

#### **Flammable:**

Do not use near heat, flame, or while smoking

#### **When using this product**

Keep out of eyes. Rinse with water to remove. Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120F.

#### **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 15 minutes before sun exposure
- Hold 4 to 6 inches away from body when spraying
- For children under 6 months of age, ask a doctor
- Do not spray directly on face and avoid breathing mist
- Spray on hand and apply to face. Use in well-ventilated areas
- **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:
  - Limit time in the sun, especially from 10a.m. - 2p.m.
  - Wear long-sleeved shirts, pants, hats and sunglasses
- Reapply:
  - after 80 minutes of swimming or sweating
  - immediately after towel use
  - at least every 2 hours

## ***Inactive Ingredients***

Aloe Barbadensis Leaf Juice, Butyloctyl Salicylate, Camellia Sinensis (Green Tea) Leaf Extract, Caprylhydroxamic Acid, Glyceryl Caprylate, Glycerin, Caprylic/Capric Triglycerides, Chamomilla Recutita (Matricaria) Flower Extract, Citric Acid, Coco-Caprylate, Fragrance, Glyceryl Oleate Citrate, Methylheptyl Isostearate, Pentylene Glycol, Polyhydroxystearic Acid, Sodium Chloride, Sorbitan Oleate, Tocopheryl Acetate, Water



**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	140 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
GLYCERYL MONOOLEATE CITRATE (UNII: NLE5KIG74K)	
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0K00R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CHAMOMILE (UNII: FGL3685T2X)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
METHYLHEPTYL ISOSTEARATE (UNII: 981F40Q9FF)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73418-104-05	142 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/30/2023	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	09/30/2023	

**Labeler** - Hello Bello (081135707)

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