ZINC OXIDE- zinc oxide stick ZINC OXIDE- 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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## **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

## **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 am. - 2 p.m. Wear long-sleeved shirts, pants, hats, and sunglasses.

## **INACTIVE INGREDIENTS:**

Helianthus Annuus (Sunflower) Seed Oil, Cocos Nucifera (Coconut) Oil\*, Euphorbia Cerifera

(Candelilla) Wax, Ricinus Communis (Castor) Seed Oil, Rubus Idaeus (Red Raspberry) Seed Oil, Butyrospermum Parkii (Shea) Butter\*, Prunus Armeniaca (Apricot) Kernel Oil, Argania Spinosa (Argan) Kernel Oil\*, Copernicia Cerifera (Carnauba) Wax\*, Rosa Canina (Rosehip) Fruit Oil, Tocopherol - \*Certified Organic

## Principal Display Panel - 29 g Box Label

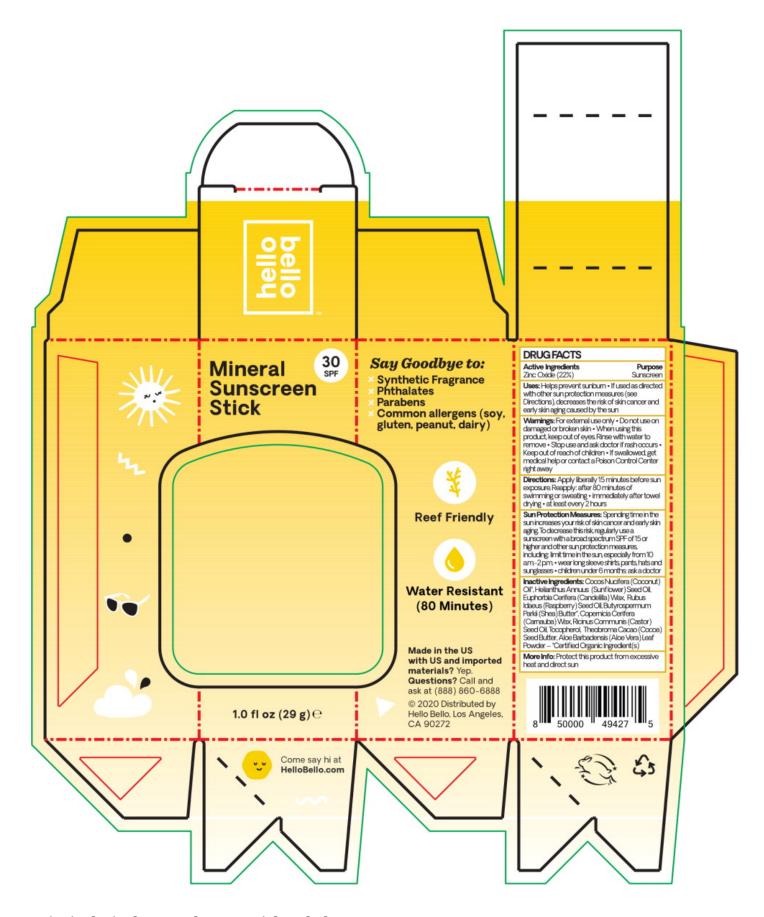
hello

bello

Mineral Sunscreen Stick

30 SPF

1.0 fl oz (29 g) e



Principal Display Panel - 29 g Stick Label

hello bello

**Mineral** 

Sunscreen Stick

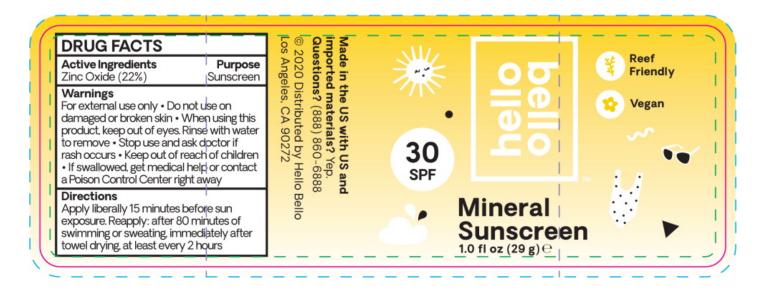
**30** 

SPF

1.0 fl oz (29 g) e

Reef Friendly

Vegan



## Principal Display Panel - 88.7 mL Carton Label

50+ SPF

**Broad Spectrum UVA + UVB Protection** 

Non- Nano Zinc Oxide

hello bello<sup>TM</sup>

- Dermatologist Tested
- Clinically Tested Non-Greasy
- Hypoallergenic

Safe & Effective for Adults & Kids

Mineral Sunscreen

3.0 fl. oz. (88.7 ml) e

Reef Friendly

Water Resistant (80 Minutes)



Hello Bello Mineral Sunscreen gives you broad spectrum protection using one simple ingredient: zinc oxide. It's the only FDA-approved sunscreen ingredient that protects against all three types of UV rays (UVB, UVA2, and UVA1)!

### **ACTIVE INGREDIENTS**

PURPOSE

Zinc Oxide - 20.0%

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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: Helianthus Annuus (Sunflower) Seed Oil, Cocos Nucifera (Coconut) Oil\*, Euphorbia Cerifera (Candelilla) Wax, Ricinus Communis (Castor) Seed Oil, Rubus Idaeus (Red Raspberry) Seed Oil, Butyrospermum Parkii (Shea) Butter\*, Prunus Armeniaca (Apricot) Kernel Oil, Argania Spinosa (Argan) Kernel Oil\*, Copernicia Cerifera (Carnauba) Wax\*, Rosa Canina (Rosehip) Fruit Oil, Tocopherol - \*Certified Organic

## Say Goodbye to:

- Synthetic Fragrance Phthalates



Made in the US with US and imported materials? Yep. Questions? Call and ask at (888) 860-6888

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Reef Friendly



Adults & Kids

Sunscreen

**Mineral** 

3.0 fl. oz. (88.7ml) ⊖

Water Resistant (80 Minutes)



## ZINC OXIDE

zinc oxide stick

#### **Product Information**

HUMAN OTC DRUG NDC:73418-020 Product Type Item Code (Source)

Route of Administration TOPICAL

## **Active Ingredient/Active Moiety**

|   | Ingredient Name  | Basis of Strength | Strength       |
|---|--|-------------------|----------------|
| ı | Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z) | Zinc Oxide        | 22 g in 100 mL |

## **Inactive Ingredients**

| Ingredient Name                       | Strength |  |  |
|---------------------------------------|----------|--|--|
| Sunflower Oil (UNII: 3W1JG795YI)      |          |  |  |
| Coconut Oil (UNII: Q9L0O73W7L)        |          |  |  |
| Candelilla Wax (UNII: WL0328HX19)     |          |  |  |
| Castor Oil (UNII: D5340 Y219 G)       |          |  |  |
| Raspberry Seed Oil (UNII: 9S8867952A) |          |  |  |
| Apricot Kernel Oil (UNII: 54JB35T06A) |          |  |  |
| Argan Oil (UNII: 4V59G5UW9X)          |          |  |  |
| Carnauba Wax (UNII: R12CBM0EIZ)       |          |  |  |
| Aloe Vera Leaf (UNII: ZY81Z83H0X)     |          |  |  |
| Tocopherol (UNII: R0ZB2556P8)         |          |  |  |

| Packaging                       |  |                         |                    |  |
|---------------------------------|--|-------------------------|--------------------|--|
| # Item Code Package Description |  | Marketing Start<br>Date | Marketing End Date |  |
| 1 NDC:73418-020                 | 1 in 1 BOX   | 0 2/0 1/20 19           |                    |  |
| 1                               | 29 mL in 1 APPLICATOR; Type 0: Not a Combination Product |                         |                    |  |

| Marketing Information |  |                      |                    |
|-----------------------|--|----------------------|--------------------|
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final   | part352                                  | 0 2/0 1/20 19        |                    |
|                       |  |                      |                    |

# ZINC OXIDE

zinc oxide lotion

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:73418-021 |
| 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 |  |  |  |
| Sunflower Oil (UNII: 3W1JG795YI)      |          |  |  |  |
| Coconut Oil (UNII: Q9L0O73W7L)        |          |  |  |  |
| Candelilla Wax (UNII: WL0328HX19)     |          |  |  |  |
| Castor Oil (UNII: D5340 Y2I9 G)       |          |  |  |  |
| Raspberry Seed Oil (UNII: 9S8867952A) |          |  |  |  |
| Apricot Kernel Oil (UNII: 54JB35T06A) |          |  |  |  |

| <u> </u>                                 |  |
|--|--|
| Argan Oil (UNII: 4V59G5UW9X)             |  |
| Carnauba Wax (UNII: R12CBM0EIZ)          |  |
| Rosa Canina Fruit Oil (UNII: CR7307M3QZ) |  |
| Tocopherol (UNII: R0 ZB2556 P8)          |  |

| Packaging |     |                 |  |                             |                    |
|-----------|-----|-----------------|--|-----------------------------|--------------------|
| ı         | #   | Item Code       | Package Description                                  | <b>Marketing Start Date</b> | Marketing End Date |
| ı         | 1 N | DC:73418-021-01 | 88.7 mL in 1 TUBE; Type 0: Not a Combination Product | 02/01/2019                  |                    |

| Marketing Information |  |                      |                    |
|-----------------------|--|----------------------|--------------------|
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final   | part352                                  | 0 2/0 1/20 19        |                    |
|                       |  |                      |                    |

# Labeler - Hello Bello (081135707)

| Establishment      |         |           |                                   |  |
|--------------------|---------|-----------|-----------------------------------|--|
| Name               | Address | ID/FEI    | Business Operations               |  |
| Unconditional Love |         | 081135707 | MANUFACTURE(73418-020, 73418-021) |  |

Revised: 1/2021 Hello Bello