

KIDS MINERAL SUNSCREEN SPF50- sunscreen 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.

Mineral Sunscreen Spray SPF50

Drug Facts

Active Ingredients

Titanium Dioxide 3.4%

Zinc Oxide 16%

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

Flammable: Do not use near heat, flame, or while smoking

Do not use on

broken or damaged skin

When using this product

Keep away from face and avoid breathing it. 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 and spread evenly by hand 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
- Spray on hand and apply to face. Use in well-ventilated areas. Do not apply in wind conditions.
- Reapply: • after 80 minutes of swimming or sweating • immediately after towel use • at least every 2 hours
- **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

Other Information

- Protect this product from excessive heat and direct sun
- May stain some fabrics

Inactive Ingredients

Water (Aqua), Butyloctyl Salicylate, Isononyl Isononanoate, Dicaprylyl Carbonate, Methyl Dihydroabietate, Propanediol, Isocetyl Stearoyl Stearate, Cetearyl Alcohol, Sodium Stearoyl Glutamate, Polyester-8, C18-21 Alkane, Silica, Alumina, Tocopherol, Bisabolol, Polyhydroxystearic Acid, Coco-Glucoside, Glycerin, Caprylyl Glycol, Caprylhydroxamic Acid, Musa Sapientum (Banana) Fruit Extract, Sodium Gluconate, Citric Acid, Aloe Barbadensis Leaf Juice, Bentonite, Microcrystalline Cellulose, Cellulose Gum

- Dermatologist Tested
- Non-Greasy • Hypoallergenic



Broad Spectrum UVA + UVB Protection
Non-Nano Zinc Oxide

Kids Mineral Sunscreen Spray

NET WT. 5.0 fl. oz. (148 ml) e



Reef Friendly



Water Resistant (80 Minutes)

Cover up and enjoy a good time outside knowing our sunscreen is helping protect and nourish your family's skin.

DRUG FACTS	
ACTIVE INGREDIENTS	PURPOSE
Titanium Dioxide - 3.4%	Sunscreen
Zinc Oxide - 16%	Sunscreen
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.	
WARNING: For external use only • Flammable: Do not use near heat, flame, or while smoking • Do not use on broken or damaged skin.	
When using this product: Keep away from face and avoid breathing it • Keep out of eyes. Rinse with water to remove • Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F • 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 • Hold 4 to 6 inches away from body when spraying • For children under 6 months of age, ask a doctor • Do not spray directly onto face • Spray on hands then apply to face • Use in well-ventilated areas • Do not apply in windy conditions • Reapply • After 80 minutes of swimming or sweating • Immediately after towel use • At least every 2 hours.	
SUN PROTECTION MEASURES: Spending time in the sun increases 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 10 a.m. - 2 p.m. Wearing long-sleeved shirts, pants, hats, and sunglasses.	
INACTIVE INGREDIENTS: Water (Aqua), Butyloctyl Salicylate, Isononyl Isononanoate, Dicaprylyl Carbonate, Methyl Dihydroabietate, Propanediol, Isocetyl Stearoyl Stearate, Cetearyl Alcohol, Sodium Stearoyl Glutamate, Polyester-8, C18-21 Alkane, Silica, Alumina, Tocopherol, Bisabolol, Polyhydroxystearic Acid, Coco-Glucoside, Glycerin, Caprylyl Glycol, Caprylhydroxamic Acid, Musa Sapientum (Banana) Fruit Extract, Sodium Gluconate, Citric Acid, Aloe Barbadensis Leaf Juice, Bentonite, Microcrystalline Cellulose, Cellulose Gum	
Other Information: Protect this product from excessive heat and direct sun • May stain some fabrics.	

Made without:

- ✗ Synthetic Fragrance ✗ Phthalates ✗ Parabens
- ✗ Chemical Sunscreens

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

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KIDS MINERAL SUNSCREEN SPF50

sunscreen spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73418-105
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	160 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	34 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
ISOCETYL STEAROYL STEARATE (UNII: IJV4LS383R)	
C18-C21 ALKANE (UNII: 33822S0M40)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
LEVOMENOL (UNII: 24WE03BX2T)	
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
TOCOPHEROL (UNII: R0ZB2556P8)	
GLYCERIN (UNII: PDC6A3C0OX)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
PROPANEDIOL (UNII: 5965N8W85T)	
COCO GLUCOSIDE (UNII: ICS790225B)	
BANANA (UNII: 4AJZ4765R9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73418-105-05	142 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/13/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	09/13/2023	

Labeler - Hello Bello (081135707)

Establishment

Name	Address	ID/FEI	Business Operations
Bell International Laboratories, Incorporated		967781555	manufacture(73418-105)

