

**OPEN NATURE CHILDREN SPF 50 MINERAL SUNSCREEN- zinc oxide lotion
SAFEWAY, INC.**

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.

OPEN NATURE CHILDREN'S SPF 50 MINERAL SUNSCREEN LOTION

Active ingredients

Zinc Oxide 21.6%

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 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
- 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:
 - limit time in the sun, especially from 10 a.m. - 2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses

Other information

- protect the product in this container from excessive heat and direct sun
- may stain or damage some fabrics, materials or surfaces

Inactive ingredients

water, C12-15 alkyl benzoate, caprylic/capric triglyceride, styrene/acrylates copolymer, octyldodecyl citrate crosspolymer, phenyl trimethicone, cetyl PEG/PPG-10/1 dimethicone, dimethicone, polyhydroxystearic acid, glycerin, ethyl methicone, cetyl dimethicone, silica, colloidal oatmeal, chrysanthemum parthenium (feverfew) flower/leaf/stem juice, glyceryl behenate, phenethyl alcohol, caprylyl glycol, bis-divinyl dimethicone PEG-10 dimethicone crosspolymer, sodium chloride, phenoxyethanol, chlorphenesin



ZINC OXIDE SUNSCREEN

CHILDREN'S MINERAL SUNSCREEN LOTION

WATER RESISTANT (80 MINUTES)

BROAD SPECTRUM SPF 50
HYPOALLERGENIC | PEDIATRICIAN TESTED
REEF CONSCIOUS* || FRAGRANCE FREE



3.0 FL OZ (89 mL)

At Open Nature® we believe products should be simple – quality products that are crafted to be gentle for the whole family. Open Nature Mineral Sunscreen Lotion provides broad-spectrum UVA & UVB sun protection that is water and sweat resistant up to 80 minutes. Trust this lightweight, soothing sunscreen to protect your child's sensitive skin.

FORMULATED WITHOUT PARABENS • NOT TESTED ON ANIMALS

*Formula is compliant with HHS 2571.

Drug Facts	
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Zinc Oxide 21.6%	Sunscreen
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Warnings	
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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.	
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OPEN NATURE CHILDREN SPF 50 MINERAL SUNSCREEN

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-725
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	216 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
OCTYLDODECYL CITRATE CROSSPOLYMER (UNII: X323T6QO4M)	
PHENYL TRIMETHICONE (UNII: DROK5NOJ4R)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYL METHICONE (8 MPA.S) (UNII: 3YWG8XYT8H)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
OATMEAL (UNII: 8PI54V663Y)	
GLYCERYL MONOBEHENATE (UNII: A626UU0W2A)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
TANACETUM PARTHENIUM FLOWER (UNII: 7TVV9D7I89)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-725-03	89 mL in 1 TUBE; Type 0: Not a Combination Product	12/05/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/05/2018	

Labeler - SAFEWAY, INC. (009137209)