

OPEN NATURE ZINC OXIDE SUNSCREEN MINERAL SUNSCREEN SPF 30- 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 Zinc Oxide Sunscreen Mineral Sunscreen Lotion SPF 30

Active ingredients

Zinc Oxide 18.24%

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, styrene/acrylates copolymer, caprylic/capric triglyceride, dimethicone, phenyl trimethicone, cetyl PEG/PPG-10/1 dimethicone, polyhydroxystearic acid, glycerin, dipropylene glycol dibenzoate, cetyl dimethicone, silica, chrysanthemum parthenium (feverfew) flower/leaf/stem juice, glyceryl behenate, phenethyl alcohol, caprylyl glycol, acrylates/dimethicone crosspolymer, PPG-15 stearyl ether benzoate, sodium chloride, phenoxyethanol, chlorphenesin



ZINC OXIDE SUNSCREEN

MINERAL SUNSCREEN LOTION

WATER RESISTANT (80 MINUTES)

BROAD SPECTRUM SPF 30
HYPOALLERGENIC | DERMATOLOGIST 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 on your skin. Open Nature Mineral Sunscreen Lotion provides effective water and sweat resistant (up to 80 minutes) broad-spectrum UVA & UVB sun protection that you can trust. This lightweight, hypoallergenic zinc oxide lotion absorbs quickly and protects sensitive skin without irritating.
*Formula is compliant with H1 SB2b71

Drug Facts	
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OPEN NATURE ZINC OXIDE SUNSCREEN MINERAL SUNSCREEN SPF 30

zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-751
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	182.4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPROPYLENE GLYCOL DIBENZOATE (UNII: 6OA5ZDY41O)	
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)	
PPG-15 STEARYL ETHER BENZOATE (UNII: 80D2J6361M)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
2-ETHYLHEXYL ACRYLATE, METHACRYLATE, METHYL METHACRYLATE, OR BUTYL METHACRYLATE/HYDROXYPROPYL DIMETHICONE COPOLYMER (30000-300000 MW) (UNII: S7ZA3CCJ4M)	
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:21130-751-09	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)