OPEN NATURE 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 SPF 50 MINERAL SUNSCREEN LOTION

Active ingredient

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, octydodecyl citrate crosspolmyer, phenyl trimethicone, cetyl PEG/PPG-10/1 dimethicone, dimethicone, glycerin, polyhydroxystearic acid, ethyl methicone, cetyl dimethicone, silica, chrysanthemum parthenium (feverfew) flower/leaf/stem juice, glyceryl behenate, phenethyl alcohol, caprylyl glycol, bis-divinyl dimethicone/PEG-10 dimethicone crosspolymer, sodium chloride, phenoxyethanol, chlorphenesin

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 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.

FORMULATED WITHOUT PARABENS • NOT TESTED ON ANIMALS

*Formula is compliant with HI SB2571.

Drug Facts

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OPEN NATURE SPF 50 MINERAL SUNSCREEN

zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:21130-723
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
GLYCERYL MONOBEHENATE (UNII: A626UU0W2A)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERIN (UNII: PDC6A3C0OX)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TANACETUM PARTHENIUM FLOWER (UNII: 7TVV9D7I89)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
WATER (UNII: 059QF0KO0R)	
ETHYL METHICONE (8 MPA.S) (UNII: 3YWG8XYT8H)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CHLORPHENESIN (UNII: I670DAL4SZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-723-03	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 final	part346	12/05/2018	

Labeler - SAFEWAY, INC. (009137209)

Revised: 1/2022 SAFEWAY, INC.