

DAILY SPF 15- avobenzone, octinoxate, octisalate lotion
THE KROGER CO

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.

KROGER BROMLEY'S FOR MEN DAILY SPF 15 MOISTURIZER

Active ingredients

Avobenzone 3.0%, Octinoxate 7.5%, Octisalate 2.0%

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

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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- reapply at least every two hours
- use a water resistant sunscreen if swimming or sweating
- 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 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-sleeve shirts, pants, hats, and sunglasses

Other information

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

Inactive ingredients

water, C12-15 alkyl benzoate, cetearyl alcohol, glycerin, aloe barbadensis leaf juice, dimethicone, glycine soja (soybean) seed extract, phenyl trimethicone, arachidyl alcohol, cetearyl glucoside, phenoxyethanol, benzyl alcohol, panthenol, ethylene/ acrylic acid copolymer, behenyl alcohol, steareth-2, steareth-21, polymethyl methacrylate, polyacrylamide, arachidyl glucoside, disodium EDTA, C13-14 isoparaffin, laureth-7, silica, benzalkonium chloride, iodopropynyl butylcarbamate, PEG-4, PEG-4 laurate, alcohol, BHT, sodium hydroxide, citric acid, mica, titanium dioxide

KROGER BROMLEY'S FOR MEN DAILY SPF 15 MOISTURIZER

BROMLEY'S
FOR MEN

SPF 15

DAILY MOISTURIZER

WITH SUNSCREEN

broad spectrum SPF 15
UVA/UVB protection

UNSCENTED

4 FL OZ (120 mL)

BROMLEY'S For Men Daily Moisturizer moisturizes and relieves dry skin as it protects from the sun's harmful UVA/UVB rays. This soothing moisturizer helps defend against the signs of aging in one easy step for brighter, healthier feeling skin. Ideal for all skin types. Lightweight formula absorbs quickly for a non-greasy feel.

Drug Facts

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Avobenzone 3%	Sunscreen
Octinoxate 7.5%	
Octisalate 2%	

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DAILY SPF 15

avobenzone, octinoxate, octisalate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30 142-879
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	20 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DOCOSANOL (UNII: 9G1OE216XY)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35JOOJ)	
ACRYLIC ACID/ETHYLENE COPOLYMER (600 MPA.S) (UNII: 1PEZ3NLY6I)	
LAURETH-7 (UNII: Z95S6G8201)	
GLYCOL DILAURATE (UNII: 9O691KKR2A)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SOYBEAN OIL (UNII: 241ATL177A)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
STEARETH-2 (UNII: V56DFE46J5)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
MICA (UNII: V8A1AW0880)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PANTHENOL (UNII: WV9CM0O67Z)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYETHYLENE GLYCOL 200 (UNII: R95B8J264J)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRVV)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
STEARETH-21 (UNII: 53J3F32P58)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PEG-4 LAURATE (UNII: AYP4VM3N1Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30 142-879-13	120 mL in 1 TUBE; Type 0: Not a Combination Product	06/07/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/07/2018	

Labeler - THE KROGER CO (006999528)

Registrant - Fruit Of The Earth, Inc. (079559467)

Establishment

Name	Address	ID/FEI	Business Operations
Fruit Of The Earth, Inc.		080086802	manufacture(30142-879)

Revised: 5/2020

THE KROGER CO