# KROGER BABY SPF 50 SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion THE KROGER COMPANY

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.

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#### KROGER BABY SPF 50 SUNSCREEN LOTION

#### Active ingredients

Avobenzone 3.0%, Homosalate 13.0%, Octisalate 5.0%, Octocrylene 7.0%, Oxybenzone 4.0%

#### **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:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- 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 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
- children under 6 months: ask a doctor

#### Other information

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

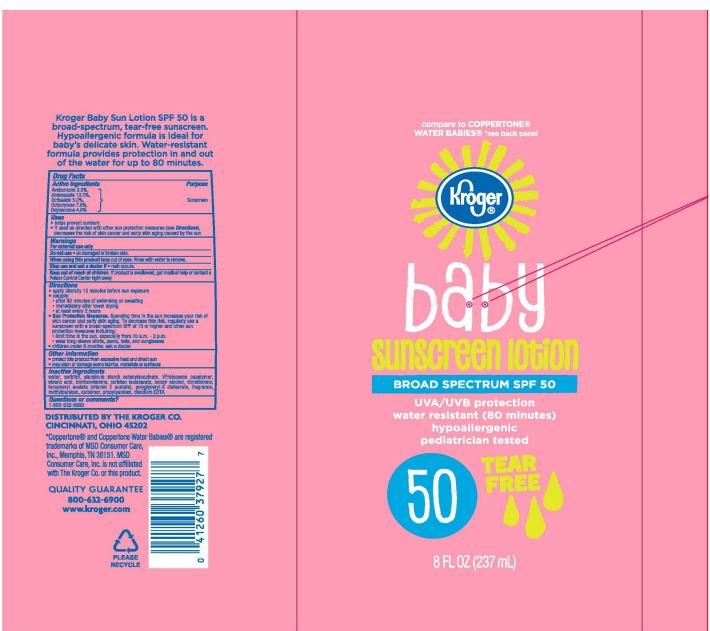
#### **Inactive ingredients**

water, sorbitol, aluminum starch octenylsuccinate, VP/eicosene copolymer, stearic acid, triethanolamine, sorbitan isostearate, benzyl alcohol, dimethicone, tocopheryl acetate (vitamin E acetate), polyglyceryl-3 distearate, fragrance, methylparaben, carbomer, propylparaben, disodium EDTA

#### Questions or comments?

1-800-632-6900

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-821
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	130 mg in 1 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	50 mg in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	70 mg in 1 mL	
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	40 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)			
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TROLAMINE (UNII: 903K93S3TK)			
METHYLPARABEN (UNII: A2I8 C7HI9 T)			
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)			
BENZYL ALCOHOL (UNII: LKG8494WBH)			
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470 XV)			
DIMETHICO NE (UNII: 92RU3N3Y1O)			
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)			

l	Packaging				
l	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
l	1 NDC:30142-821-12	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2016		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	11/30/2016		

## Labeler - THE KROGER COMPANY (006999528)

### **Registrant -** FRUIT OF THE EARTH, INC. (079559467)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
FRUIT OF THE EARTH, INC.		080086802	manufacture (30 142-821)	

Revised: 5/2020 THE KROGER COMPANY