

HEB BROAD SPECTRUM SPF 30 COCONUT SCENTED SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene stick
H.E.B

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.

HEB BROAD SPECTRUM SPF 30 COCONUT SCENTED SUNSCREEN LIP BALM

Active ingredients

Avobenzone 3.0%, Homosalate 10.0%, Octisalate 5.0%, Octocrylene 5.0%

Purpose

Sunscreen

Uses

- helps prevent sunburn

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

C12-15 alkyl benzoate, paraffin, butyloctyl salicylate, synthetic wax, ozokerite, euphorbia cerifera (candelilla) wax, dimethicone, aloe barbadensis leaf juice, mineral oil, ascorbyl palmitate, tocopheryl acetate, dimethicone crosspolymer-3, cetyl dimethicone, cetyl alcohol, caprylyl glycol.

Questions of comments?

Call toll free 1-800-527-7731

NDC 37808-931-89

Great for Everyday, Year round use
Retinyl Palmitate Free • Contains Vitamin E, and Aloe Vera

Drug Facts

Active ingredients

Avobenzone 3%,
Homosalate 10%,
Octisalate 5,
Octocrylene 5%

Purpose

Sunscreen

Uses • helps prevent sunburn

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 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

C12-15 alkyl benzoate, paraffin, butyloctyl salicylate, synthetic wax, ozokerite, euphorbia cerifera (candelilla) wax, dimethicone, flavor, aloe barbadensis leaf extract, mineral oil, ascorbyl palmitate, tocopheryl acetate, dimethicone crosspolymer-3, cetyl dimethicone, cetyl alcohol, caprylyl glycol.

Questions or Comments? Call toll free 1-800-527-7731

**MADE WITH PRIDE
AND CARE FOR H-E-B®,
SAN ANTONIO,
TEXAS 78204**



9569-1902





HEB BROAD SPECTRUM SPF 30 COCONUT SCENTED SUNSCREEN
 avobenzone, homosalate, octisalate, octocrylene stick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-931
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 g
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	50 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CANDELILLA WAX (UNII: WL0328HX19)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PARAFFIN (UNII: I9O0E3H2ZE)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CERESIN (UNII: Q1LS2UJO3A)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MINERAL OIL (UNII: T5L8T28FGP)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-931-89	2 in 1 CARTON	04/03/2019	
1	NDC:37808-931-58	0.15 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/03/2019	

Labeler - H.E.B (007924756)**Registrant** - Fruit of the Earth, Inc. (079559467)**Establishment**

Name	Address	ID/FEI	Business Operations
Fruit Of The Earth Research Laboratories, Inc.		008193513	manufacture(37808-931)

