# HEB BROAD SPECTRUM SPF 30 BANANA 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 BANANA SCENTED SUNSCREEN LIP BALM

#### Active ingredients

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

## **Purpose**

Sunscreen

#### $\Pi Uses$

• helps prevent sunburn

## **Warnings**

#### **IFor 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 if1** • 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





#### HEB BROAD SPECTRUM SPF 30 BANANA SCENTED SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene stick

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-933	
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: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	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	

Ingredient Name CANDELILLA WAX (UNII: WL0328 HX19)  ALKYL (C12-15) BENZOATE (UNII: A9EJ3J6 1HQ)  PARAFFIN (UNII: 1900 E3H2ZE)  BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8 D3)  CERESIN (UNII: Q1LS2UJO3A)  YELLOW WAX (UNII: 2ZA36 H0 S2V)  CETYL DIMETHICONE 25 (UNII: U4AS 1BW4ZB)  CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)  CETYL ALCOHOL (UNII: 936JST6JCN)  MINERAL OIL (UNII: T5L8 T28 FGP)
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)  PARAFFIN (UNII: 1900E3H2ZE)  BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)  CERESIN (UNII: Q1LS2UJO3A)  YELLOW WAX (UNII: 2ZA36H0S2V)  CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)  CAPRYLYL GLYCOL (UNII: 00YIU5438U)  CETYL ALCOHOL (UNII: 936JST6JCN)
PARAFFIN (UNII: 1900E3H2ZE) BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3) CERESIN (UNII: Q1LS2UJO3A) YELLOW WAX (UNII: 2ZA36H0S2V) CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB) CAPRYLYL GLYCOL (UNII: 00 YIU5438U) CETYL ALCOHOL (UNII: 936JST6JCN)
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8 D3)  CERESIN (UNII: Q1LS2UJO3A)  YELLOW WAX (UNII: 2ZA36H0 S2V)  CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)  CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)  CETYL ALCOHOL (UNII: 936JST6JCN)
CERESIN (UNII: Q1LS2UJO3A)  YELLOW WAX (UNII: 2ZA36H0S2V)  CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)  CAPRYLYL GLYCOL (UNII: 00 YIU5438U)  CETYL ALCOHOL (UNII: 936JST6JCN)
YELLOW WAX (UNII: 2ZA36H0S2V)  CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)  CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)  CETYL ALCOHOL (UNII: 936JST6JCN)
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)  CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)  CETYL ALCOHOL (UNII: 936JST6JCN)
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U) CETYL ALCOHOL (UNII: 936JST6JCN)
CETYL ALCOHOL (UNII: 936JST6JCN)
MINERAL, O.H. (LINII: T51.8T28EGP)
WHITE OE (ONE 15E01251GI)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)
DIMETHICO NE (UNII: 92RU3N3Y1O)

	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:37808-933- 89	2 in 1 CARTON	0 4/0 4/20 19	
	1	NDC:37808-933-58	0.15 g in 1 CONTAINER; Type 0: Not a Combination Product		
ш					

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

## **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(37808-933)

Revised: 5/2020 HE.B