

FRUIT OF THE EARTH CABANA BEACH CLUB LIP BALM WITH MANUKA HONEY AND ESSENTIAL OILS SPF 30- avobenzone, homosalate, octisalate, octocrylene stick
Fruit of the Earth, 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.

Fruit of the Earth Cabana Beach Club Lip Balm with Manuka Honey and Essential Oils SPF 30

Active ingredients

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

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 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 extract, mineral oil, ascorbyl palmitate, honey (manuka honey), bertholletia excelsa seed oil (brazil nut), vaccinium macrocarpon (cranberry) seed oil, tocopheryl acetate, dimethicone crosspolymer-3, cetyl dimethicone, cetyl alcohol, caprylyl glycol, fragrance.

DIRECTIONS: Apply liberally to all exposed areas 15 minutes before sun exposure.

WARNINGS: FOR EXTERNAL USE ONLY. May stain some fabrics. Avoid getting in eyes. Rinse with water to remove. If rash or irritation occurs and continues, stop using and consult a doctor. **KEEP OUT OF REACH OF CHILDREN.**

ACTIVE INGREDIENTS: Avobenzone 3.0%, Homosalate 10.0%, Octisalate 5.0%, Octocrylene 5.0%.

PARABEN & PHTHALATE FREE*
NO REEF-HARMING OXYBENZONE & OCTINOXATE†

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At Fruit of the Earth, we pride ourselves in being 100% American owned and operated.
Fruit of the Earth, Inc.
3325 W. Trinity Blvd.
Grand Prairie, TX 75050



Broad Spectrum SPF 30 protection & Water Resistant (80 minutes)
*No parabens separately added to preserve this product.
†Formula is compliant with Hawaii SB2571.

NET WT 0.15 OZ (4.25 g)
Questions? Call 1-800-527-7731



with manuka honey + essential oils
SPF 30

OVERLAP AREA



FRUIT OF THE EARTH CABANA BEACH CLUB LIP BALM WITH MANUKA HONEY AND ESSENTIAL OILS SPF 30

avobenzone, homosalate, octisalate, octocrylene stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62217-083
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	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

Inactive Ingredients

Ingredient Name	Strength
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)	
BRAZIL NUT OIL (UNII: 0G89T29HO6)	
HONEY (UNII: Y9H1V576FH)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PARAFFIN (UNII: I9O0E3H2ZE)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CANDELILLA WAX (UNII: WL0328HX19)	
CERESIN (UNII: Q1LS2UJO3A)	
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:62217-083-59	1 in 1 BLISTER PACK	05/30/2018	
1	NDC:62217-083-58	4.25 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	05/30/2018	

Labeler - Fruit of the Earth, Inc. (079559467)