

**AFFINIA FACIAL MOISTURIZER- avobenzene, homosalate, octisalate, octocrylene lotion**  
**Melaleuca, 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.*

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**Affinia Facial Moisturizer**

**Active ingredients**

Avobenzene 1.8%, Homosalate 6%, Octisalate 3%, Octocrylene 5%

**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 Poison Control Center right away.

**Directions**

For sunscreen use:

- apply smoothly on cleansed skin
- apply liberally 15 minutes before sun exposure
- use a water-resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: 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 10a.m.-2p.m.
  - wear long-sleeve shirts, pants, hats, and sunglasses

### **Other information**

- for normal-to-dry skin
- dermatologist and allergy tested
- may stain some fabrics
- protect this product from excessive heat and direct sun
- do not store at temperatures below 32°F (0°C) or above 120°F (49°C)

### **Inactive ingredients**

Ammonium Acryloyldimethyltaurate/VP Copolymer, Aqua (Water/Eau), Butyrospermum Parkii (Shea Butter), Calcium Pantothenate, Cetyl Alcohol, Citric Acid, Dimethicone, Glycerin, Glyceryl Stearate, Maltodextrin, Mangifera Indica (Mango) Seed Butter, Methylisothiazolinone, Niacinamide, Parfum, PEG-100 Stearate, Phenoxyethanol, Phenoxyethyl Caprylate, Polyacrylate-15 (and) Polyacrylate-17, Potassium Sorbate, Pyridoxine HCL, Silica, Sodium Ascorbyl Phosphate, Sodium Starch Octenylsuccinate, Sodium Stearoyl Glutamate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Trisodium Ethylenediamine Disuccinate, Xanthan Gum



## AFFINIA FACIAL MOISTURIZER

avobenzone, homosalate, octisalate, octocrylene lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54473-224
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7.296 g in 120 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	6.08 g in 120 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	3.648 g in 120 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.1888 g in 120 mL

### Inactive Ingredients

Ingredient Name	Strength
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<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER</b> (UNII: W59H9296ZG)
<b>CALCIUM PANTOTHENATE</b> (UNII: 568ET80C3D)
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)
<b>MANGIFERA INDICA SEED BUTTER</b> (UNII: 4OXD9M35X2)
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>PHENOXYETHYL CAPRYLATE</b> (UNII: GMI5AN7T8U)
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV)
<b>SHEANUT OIL</b> (UNII: O88E196QRF)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>SODIUM ASCORBYL PHOSPHATE</b> (UNII: 836SJG51DR)
<b>SODIUM STEAROYL GLUTAMATE</b> (UNII: 65A9F4P024)
<b>TRISODIUM ETHYLENEDIAMINE DISUCCINATE</b> (UNII: YA22H34H9Q)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-224-04	1 in 1 BOX	01/01/2018	
1	NDC:54473-224-01	120 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		



## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/01/2012	

**Labeler** - Melaleuca, Inc. (139760102)

**Registrant** - Melaleuca, Inc. (139760102)

## Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca, Inc.		079711683	manufacture(54473-224)

Revised: 1/2023

Melaleuca, Inc.