

**FACE VALUES ULTRA SPORT ACTIVE SPF 50 SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene lotion**  
**HARMON STORES, 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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**FACE VALUES ULTRA SPORT ACTIVE SPF 50 SUNSCREEN LOTION**

***Active ingredients***

Avobenzone 3.0%, Homosalate 10.0%, Octisalate 4.5%, Octocrylene 8.0%

***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, glycerin, polyester-7, neopentyl glycol diheptanoate, aluminum starch octenylsuccinate, silica, styrene/acrylates copolymer, phenoxyethanol, isododecane, arachidyl alcohol, ethylhexylglycerin, acrylates/C10-30 alkyl acrylate crosspolymer, behenyl alcohol, tocopherol (vitamin E), beeswax, arachidyl glucoside, potassium hydroxide, glyceryl stearate, PEG-100 stearate, disodium EDTA, sodium ascorbyl phosphate, fragrance

***Questions or comments?***

1-800-527-7731

FACE VALUES ULTRA SPORT ACTIVE SPF 50 SUNSCREEN LOTION

3 FL OZ (88.7mL)

NDC 63940-068-09

# FACE VALUES™

Compare to Coppertone® Sport® Sunscreen Lotion\*

## Ultra Sport Active Sunscreen Lotion

**50** Broad Spectrum SPF 50

- Reef conscious formula†
- Octinoxate, oxybenzone & paraben free\*\*
- Light, breathable feel
- Water Resistant (80 minutes)

3.0 FL OZ (88.7 mL)

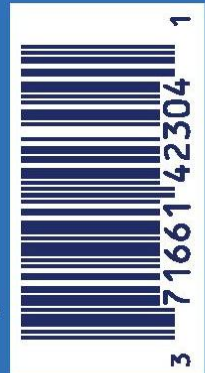
Drug Facts	
<b>Active ingredients</b>	<b>Purpose</b>
Avobenzone 3.0% Homosalate 10.0% Octisalate 4.5% Octocrylene 8.0%	Sunscreen
<b>Uses</b> • helps prevent sunburn • If used as directed with other sun protection measures (see <i>Directions</i> ), decreases the risk of skin cancer and early skin aging caused by the sun	
<b>Warnings</b>	
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.	
<b>Directions</b>	
• 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	
<b>Other information</b>	
• protect the product in this container from excessive heat and direct sun	
• may stain or damage some fabrics, materials or surfaces	
<b>Inactive ingredients</b>	
water, polyester-7, neopentyl glycol diisopanoate, glycerin, styrene/acrylates copolymer, aluminum starch octylsuccinate, silica, phenoxyethanol, isododecane, arachidyl alcohol, beeswax, ethylhexylglycerin, acrylate/C10-30 alkyl acrylate crosspolymer, behenyl alcohol, tocopherol (vitamin E), arachidyl glucoside, glyceryl stearate, PEG-100 stearate, potassium hydroxide, disodium EDTA, sodium ascorbyl phosphate, fragrance	
<b>Questions or comments?</b> 1-800-527-7731	

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Visit us at:  
[www.facevalues.com](http://www.facevalues.com)

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\*This product is not manufactured or distributed by Bayer HealthCare, LLC, owner of the registered trademarks Coppertone® and Coppertone Sport®.

†Formula is compliant with HHSB2571.  
\*\*No parabens separately added to preserve this product



### FACE VALUES ULTRA SPORT ACTIVE SPF 50 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63940-068
Route of Administration	TOPICAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL

<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	45 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	80 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYESTER-7</b> (UNII: 0841698D2F)	
<b>NEOPENTYL GLYCOL DIHEPTANOATE</b> (UNII: 5LKW3C543X)	
<b>ALUMINUM STARCH OCTENYLSUCCINATE</b> (UNII: I9PJ0O6294)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>ARACHIDYL ALCOHOL</b> (UNII: 1QR1QRA9BU)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
<b>DOCOSANOL</b> (UNII: 9G1OE216XY)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>ARACHIDYL GLUCOSIDE</b> (UNII: 6JVV35JOOJ)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>SODIUM ASCORBYL PHOSPHATE</b> (UNII: 836SJG51DR)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63940-068-09	88.7 mL in 1 TUBE; Type 0: Not a Combination Product	04/06/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/06/2017	

**Labeler** - HARMON STORES, INC. (804085293)

**Registrant** - FRUIT OF THE EARTH, INC. (008193513)

### Establishment

Name	Address	ID/FEI	Business Operations
FRUIT OF THE EARTH, INC.		079559467	manufacture(63940-068)