

**CARDINAL HEALTH LEADER SPF 30 GENERAL PROTECTION SUNSCREEN CLEAR CONTINUOUS- avobenzone, homosalate, octisalate, octocrylene, oxybenzone aerosol, spray  
Cardinal Health, 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.*

-----  
**Cardinal Health Leader SPF 30 General Protection Sunscreen Clear Continuous Spray**

**Active ingredients**

Avobenzone 3.0%, Homosalate 10.0%, Octisalate 5.0%, Octocrylene 2.0%, Oxybenzone 4.0%

**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**

**FLAMMABLE:**

- do not use near heat, flame or while smoking
- avoid long term storage above 104°F (40°C)

**Do not use**

- on damaged or broken skin

**When using this product** • keep out of eyes. Rinse with water to remove. • keep away from face to avoid breathing it. • do not puncture or incinerate. Contents under pressure. • do not store at temperatures above 120° F.

**Stop use and ask doctor if**

- rash occurs.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- spray liberally and spread evenly by hand 15 minutes before sun exposure
- hold can 4-6 inches away from skin to apply
- do not spray directly into face. Spray into hand and then apply to face.
- do not apply in windy conditions
- use in well-ventilated area

- 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**

alcohol denat. (76.2% v/v), acrylates/octylacrylamide copolymer, stearoxytrimethylsilane, glycerin, diethylhexyl syringylidenemalonate, tocopherol (vitamin E), retinyl palmitate (vitamin A), fragrance, caprylic/capric triglyceride

### **Questions or comments?**

Call toll free 1-800-527-7731

Cardinal Health Leader SPF 30 General Protection Sunscreen Clear Continuous Spray

NDC: 70000-0327-1

NET WT 5.5 OZ (156 g)

**LEADER**<sup>TM</sup>

NDC 70000-0327-1

# General Protection Sunscreen

## Clear Continuous Spray

# 30

**Broad Spectrum  
SPF 30**

Quick and Even  
Coverage

Water Resistant  
(80 Minutes)

Protection From Harmful  
UVB/UVA Rays

**COMPARE TO  
COPPERTONE<sup>®</sup>  
ULTRA GUARD<sup>®</sup>  
SPF 30  
active ingredients\***

**100% Money  
Back Guarantee**

NET WT 5.5 OZ (156 g)

<b>Drug Facts</b>	
<b>Active ingredients</b>	<b>Purpose</b>
Avobenzone 3.0% Homosalate 10.0% Octisalate 5.0% Octocrylene 2.0% Oxybenzone 4.0%	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	
<b>FLAMMABLE:</b>	
<ul style="list-style-type: none"> <li>• do not use near heat, flame or while smoking</li> <li>• avoid long term storage above 104°F (40°C)</li> </ul>	
<b>Do not use</b> • on damaged or broken skin.	
<b>When using this product</b> • keep out of eyes. Rinse with water to remove. • keep away from face to avoid breathing it. • do not puncture or incinerate. Contents under pressure. • do not store at temperatures above 120°F.	
<b>Stop use and ask a doctor if</b> • rash occurs.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• spray liberally and spread evenly by hand 15 minutes before sun exposure</li> <li>• hold can 4-6 inches away from skin to apply</li> <li>• do not spray directly into face. Spray into hand and then apply to face.</li> <li>• do not apply in windy conditions</li> <li>• use in well-ventilated area</li> <li>• reapply:               <ul style="list-style-type: none"> <li>• after 80 minutes of swimming or sweating</li> <li>• immediately after towel drying</li> <li>• at least every 2 hours</li> </ul> </li> <li>• children under 6 months of age: ask a doctor</li> <li>• <b>Sun Protection Measures.</b> 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:               <ul style="list-style-type: none"> <li>• limit time in the sun, especially from 10 a.m. - 2 p.m.</li> <li>• wear long-sleeve shirts, pants, hats, and sunglasses</li> </ul> </li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>• protect this product from excessive heat and direct sun</li> <li>• may stain or damage some fabrics, materials or surfaces</li> </ul>	
<b>Inactive ingredients</b>	
alcohol denat. (76.2% v/v), acrylates/octylacrylamide copolymer, stearoxytrimethylsilane, glycerin, diethylhexyl syringylidenemalonate, tocopherol (vitamin E), raffinyl palmitate (vitamin A), fragrance, caprylic/capric triglyceride	
<b>Questions or comments?</b>	
Call toll free 1-800-527-7731	

\*This product is not manufactured or distributed by Bayer Healthcare LLC, owner of the registered trademarks Coppertone<sup>®</sup> and Coppertone Ultra Guard<sup>®</sup>.

DISTRIBUTED BY CARDINAL HEALTH  
DUBLIN, OHIO 43017  
www.myLeader.com 1-800-200-6313  
Essential to Care<sup>™</sup> since 1979

© 2017 Cardinal Health. All Rights Reserved. CARDINAL HEALTH, the Cardinal Health LOGO, LEADER, and the Leader LOGO are trademarks or registered trademarks of Cardinal Health. All other marks are the property of their respective owners.

**CIN 5394267 REV. 1/18**

ALL LEADER<sup>™</sup> Brand Products Have A 100% Money Back Guarantee

Return to place of purchase if not satisfied.

DOT-SP 14786  
M5655

0 96295 13291 5

<b>CARDINAL HEALTH LEADER SPF 30 GENERAL PROTECTION SUNSCREEN CLEAR CONTINUOUS</b>			
avobenzone, homosalate, octisalate, octocrylene, oxybenzone aerosol, spray			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0327
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name	Basis of Strength	Strength	
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1g	
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1g	
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1g	

<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	20 mg in 1 g
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	40 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW)</b> (UNII: JU3XHR8VWK)	
<b>STEAROXYTRIMETHYLSILANE</b> (UNII: 9862TW94B2)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>DIETHYLHEXYL SYRINGYLIDENEMALONATE</b> (UNII: 3V5U97P248)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0327-1	156 g in 1 CAN; Type 0: Not a Combination Product	02/20/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/20/2018	

**Labeler** - Cardinal Health, Inc. (097537435)

**Registrant** - Fruit Of The Earth, Inc. (079559467)

### Establishment

Name	Address	ID/FEI	Business Operations
Fruit Of The Earth Research Laboratories, Inc.		008193513	manufacture(70000-0327)

Revised: 2/2018

Cardinal Health, Inc.