

**CARDINAL HEALTH LEADER SPF 70 GENERAL PROTECTION SUNSCREEN CLEAR CONTINUOUS- avobenzene, 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 70 General Protection Sunscreen Clear Continuous Spray

Active ingredients

Avobenzene 3.0%, Homosalate 15.0%, Octisalate 5.0%, Octocrylene 10.0%, Oxybenzone 6.0%

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. (73.2% v/v), acrylates/octylacrylamide copolymer, glycerin, diethylhexyl syringylidenemalonate, fragrance, caprylic/capric triglyceride

Questions or comments?

Call toll free 1-800-527-7731

Cardinal Health Leader SPF 70 General Protection Sunscreen Clear Continuous Spray

NDC: 70000-0326-1

NET WT 5.5 OZ (156 g)

LEADER[™]

NDC 70000-0326-1

General Protection Sunscreen Clear Continuous Spray

70

Broad Spectrum
SPF 70

Quick and Even
Coverage

Water Resistant
(80 Minutes)

Protection From Harmful
UVB/UVA Rays

COMPARE TO
COPPERTONE[®]
ULTRA GUARD[®]
SPF 70
active ingredients*

100% Money
Back Guarantee

NET WT 5.5 OZ (156 g)

Drug Facts

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Avobenzone 3.0% Homosalate 15.0% Octisalate 5.0% Octocrylene 10.0% Oxybenzone 6.0%	Sunscreen

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- spray liberally and spread evenly by hand 15 minutes before sun exposure
- hold can 4-8 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
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 - 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:
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CardinalHealth[™]

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CIN 5394259 REV. 1/18



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0326
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 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	150 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	60 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0326-1	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(70000-0326)

Revised: 2/2018

Cardinal Health, Inc.