LEADER GENERAL PROTECTION SPF 30- homosalate, octisalate, oxybenzone, octocrylene, avobenzone aerosol, spray
Cardinal Health

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.

Leader General Protection SPF 30 Continuous Spray Sunscreen

Active Ingredients

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

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 deg F (40 degC)

Do not use

on damaged or broken skin

When using this product

keep out of eyes. Rinse with water to remove. Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120 deg F.

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

Hold can 4-6 inches away form body, spray evenly to ensure complete coverage

Do not spray into face. Spray into hand and apply to face.

Use in well ventilated, but not windy areas

Reapply:

After 80 minutes of swimming or sweating

Immdiately 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 theis 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 am - 2 pm

wear long sleeve shirts, pants, hats, and sunglasses

Inactive Ingredients

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

Questions or Comments?

Call toll free 1-800-200-6313

Leader General Protection SPF 30 Continuous Spray Sunscreen

Product NDC 37205-731

LEADER GENERAL PROTECTION SPF 30

homosalate, octisalate, oxybenzone, octocrylene, avobenzone aerosol, spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37205-731
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	20 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	40 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-731-30	177 mL in 1 CAN; Type 0: Not a Combination Product	01/15/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/15/2012	

Labeler - Cardinal Health (097537435)

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

Establishment

Name	Address	ID/FEI	Business Operations
Fruit Of The Earth Research Laboratories, Inc.		008193513	manufacture(37205-731)

Revised: 12/2019 Cardinal Health