

**LEADER BABY SUNSCREEN SPF 50- avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion**  
**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.*

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**Leader Baby Sunscreen Moisturizing Lotion SPF 50**

**Active Ingredients**

Avobenzone 3.0%, Homosalate 13.0%, Octisalate 5.0%, Octocrylene 7.0% 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

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 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

## Inactive Ingredients

water, sorbitol, aluminum starch octenylsuccinate, VP/eicosene copolymer, stearic acid, triethanolamine, sorbitan isostearate, benzyl alcohol, dimethicone, tocopherol (vitamin E), polyglyceryl-3 distearate, fragrance, methylparaben, carbomer, propylparaben, disodium EDTA

## Other information

- protect this product from excessive heat and direct sun
- may stain or damage some fabrics, materials or surfaces

## Questions or Comments?

Call toll free 1-800-527-7731

## Image of Label



## LEADER BABY SUNSCREEN SPF 50

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## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37205-721
<b>Route of Administration</b>	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	130 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	70 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	40 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TOCOPHEROL (UNII: R0ZB2556P8)	
POLYGLYCERYL-3 DISTEARATE (UNII: Z11LK470XV)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-721-34	237 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**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Fruit Of The Earth Research Laboratories, Inc.		008193513	manufacture(37205-721)

Revised: 11/2019

Cardinal Health