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

Leader Baby SPF 50 Lotion

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.

Stop use and ask a doctor if

• rash occurs.

When using this product keep out of eyes.

Rinse with water to remove

Keep out of reach of children.

If 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
• 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

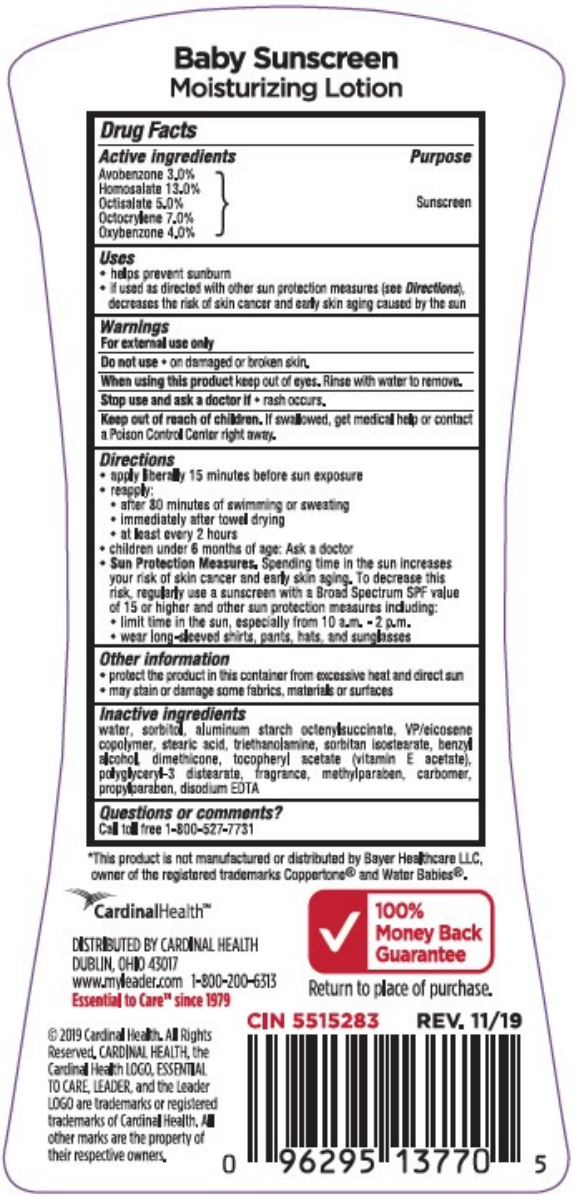
Other information

• protect the product in this container from excessive heat and direct sun
• may stain or damage some fabrics, materials or surfaces

Inactive ingredients

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

Label



Baby Sunscreen
Moisturizing Lotion

Drug Facts

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Octisalate 5.0%
Octocrylene 7.0%
Oxybenzone 4.0%
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Questions or comments?
Call toll free 1-800-527-7731

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LEADER BABY SPF 50

avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0016
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	40 mg in 1 mL
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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470XV)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SORBITOL (UNII: 506T60A25R)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0016-1	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/30/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/30/2019	

Labeler - CARDINAL HEALTH, INC. (063997360)

Revised: 11/2022 CARDINAL HEALTH, INC.