

**CARDINAL HEALTH LEADER BABY SUNSCREEN SPF 50- avobenzone, homosalate, octisalate, octocrylene 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.*

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**Cardinal Health Leader Baby Sunscreen SPF 50 Moisturizing Lotion**

**Active ingredients**

Avobenzone 3.0%, Homosalate 15.0%, Octisalate 5.0%, Octocrylene 5.0%

**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 a doctor if**

- rash occurs.

**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, tridecyl salicylate, propylene glycol, styrene/acrylates copolymer, polyamide-8, neopentyl glycol diheptanoate, oleth-3, acrylates/C10-30 alkyl acrylate crosspolymer, triethanolamine, tocopherol, disodium EDTA, chlorphenesin, benzyl alcohol, fragrance.

## **Label**

Cardinal Health Leader Baby Sunscreen SPF 50 Moisturizing Lotion

8 FL OZ (237 mL)

NDC 70000-0076-1



## CARDINAL HEALTH LEADER BABY SUNSCREEN SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0076
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50 mg in 1 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	150 mg in 1 g
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKWBC543X)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
OLETH-3 (UNII: BQZ26235UC)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
TROLAMINE (UNII: 9O3K93S3TK)	
POLYAMIDE-8 (4500 MW) (UNII: 77723GV81A)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
BUTYL METHACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID/STYRENE CROSSPOLYMER (UNII: V5RS026Q0H)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0076-1	237 g in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/11/2020	

**Labeler** - CARDINAL HEALTH, INC. (063997360)

Revised: 11/2022

CARDINAL HEALTH, INC.