BABY- sunscreen lotion Amazon.com Services LLC

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.

Sunscreen for Babies SPF 50 950.000/950AA

active ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 4.5%

Octocrylene 8%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (See **Directions**), decreases the rist 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 right away.

Directions

- apply liberally {and evenly} 15 minutes before sun exposure
- apply to all skin exposed to the sun
- 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 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
- children under 6 months of age: Ask a doctor

Other information

• protect the product in this container from excessive heat and direct sun

inactive ingredients

water, glycerin, aluminum starch octenylsuccinate, styrene/acrylates copolymer, behenyl alcohol, glyceryl stearate, benzyl alcohol, PEG-100 stearate, polyester-7, tocopherol, arachidyl alcohol, acrylates/C10-30 alkyl acrylate crosspolymer, arachidyl glucoside, chlorphenesin, beeswax, silica, neopentyl glycol diheptanoate, potassium hydroxide, disodium EDTA

May stain or damage some fabrics or surfaces

"Alexa, reorder Amazon Basics Baby Sunscreen." alexa

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principal display panel

SOLIMO

Baby Sunscreen Lotion

BROAD SPECTRUM SPF 50

Water resistant (80 minutes)

Pediatrician tested

Non-irritating



amazon basics

baby

sunscreen

lotion

Broad Spectrum SPF 50

Water Resistant (80 minutes)

Pediatricain Tested

Non-Irritating

Oxybenzone & Octinoxate Free

SPF 50

8FL OZ (236 mL)



8 FL OZ (236 mL)

BABY

sunscreen lotion

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:72288-950

Route of Administration TOPICAL

Active Ingredient/Active Moiety

ı	Ingredient Name	Basis of Strength	Strength
ı	AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	30 mg in 1 mL

Homosalate (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	Homosalate	100 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	45 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	80 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ0O6294)	
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)	
DOCOSANOL (UNII: 9G10E216XY)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYESTER-7 (UNII: 0841698D2F)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ)	
CHLORPHENESIN (UNII: 1670DAL4SZ)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
neopentyl glycol diheptanoate (UNII: 5LKW3C543X)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
			236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/08/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	09/08/2019	

Labeler - Amazon.com Services LLC (128990418)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon. LLC		790752542	manufacture(72288-950)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon. LLC		088520668	manufacture(72288-950)

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