

BABY SUNSCREEN SPF 50 TUGABOOS- avobenzone - 3.0% homosalate - 13.0% octisalate - 5.0% octocrylene - 7.0% oxybenzone 4% lotion

Rite Aid

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.

Active ingredients	Purpose
Avobenzone 3.0%.....	Sunscreen
Homosalate 13.0%.....	Sunscreen
Octisalate 5.0%.....	Sunscreen
Octocrylene 7.0%.....	Sunscreen
Oxybenzone 4.0%.....	Sunscreen

Uses • helps prevent sunburn

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 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

Aluminum Starch, Octenylsuccinate, Benzyl Alcohol, Carbomer, Dimethicone, Disodium EDTA, Fragrance, Methylparaben, Polyglyceryl-3 Distearate, Propylparaben, Sorbitan Isostearate, Sorbitol, Stearic Acid, Tocopherol, Triethanolamine, VP/Eicosene Copolymer, Water



baby sunscreen lotion

**BROAD SPECTRUM
SPF 50**



- UVA/UVB protection
- water resistant (80 minutes)

8 FL OZ (236 mL)

Drug Facts

Active ingredients	Purpose
Avobenzone 3%	Sunscreen
Homosalate 13%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 7%	Sunscreen
Oxybenzone 4%	Sunscreen

Uses • helps prevent sunburn

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 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

Other information • protect this product from excessive heat and direct sun.

Inactive ingredients Water, Sorbitol, Aluminum Starch Octenylsuccinate, VP/Eicosene Copolymer, Stearic Acid, Polyglyceryl-3 Distearate, Sorbitan Isostearate, Triethanolamine, Benzyl Alcohol, Dimethicone, Carbomer, Methylparaben, Disodium EDTA, Propylparaben, Tocopherol, Fragrance.



**DISTRIBUTED BY: RITE AID
30 HUNTER LANE
CAMP HILL, PA 17011
MADE IN USA**



**IF YOU'RE NOT
SATISFIED, WE'LL
HAPPILY REFUND
YOUR MONEY.**

BABY SUNSCREEN SPF 50 TUGABOOS

avobenzone - 3.0% homosalate - 13.0% octisalate - 5.0% octocrylene - 7.0% oxybenzone 4% lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-7789
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

Avobenzone (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	Avobenzone	3 g in 100 mL
Homosalate (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	Homosalate	13 g in 100 mL
Octisalate (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	Octisalate	5 g in 100 mL
Octocrylene (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	Octocrylene	7 g in 100 mL
Oxybenzone (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	Oxybenzone	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Aluminum Starch Octenylsuccinate (UNII: I9PJ0O6294)	
Benzyl Alcohol (UNII: LKG8494WBH)	
CARBOMER HOMO POLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
Dimethicone (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
Methylparaben (UNII: A218C7H9T)	
Polyglyceryl-3 Distearate (UNII: Z11LK470XV)	
Propylparaben (UNII: Z8IX2SC1OH)	
Sorbitan Isostearate (UNII: 01S2G2C1E4)	
Sorbitol (UNII: 506T60A25R)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Tocopherol (UNII: R0ZB2556P8)	
TROLAMINE (UNII: 9O3K93S3TK)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-7789-6	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/26/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/26/2016	

Labeler - Rite Aid (014578892)

Registrant - Product Quest Mfg. (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg.		927768135	manufacture(11822-7789)