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

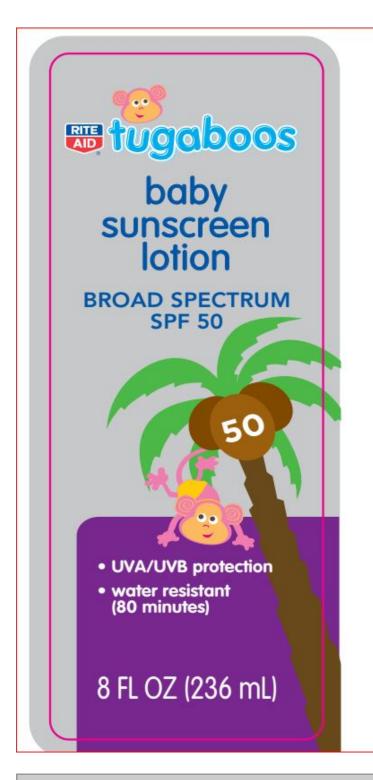
For external use only
Do not use on damaged or broken skin
When using this product keep out of eyes.
Rinse with water to remove.
Stop use and ask a doctor if rash occurs
Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

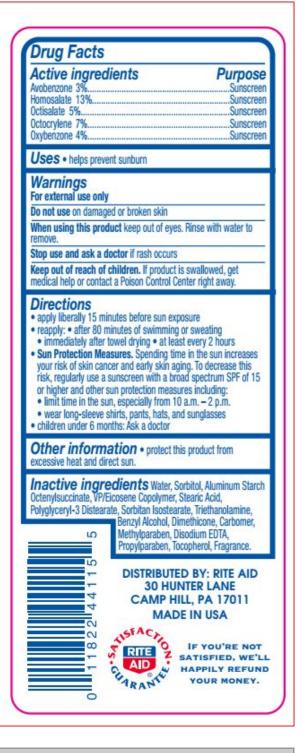
Directions

- 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





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

	Active Ingredient/Active Moiety		
l	Ingredient Name	Basis of Strength	Strength

Avobenzone (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	Avobenzone	3 g in 100 mL
Homosalate (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	Ho mo sa la te	13 g in 100 mL
Octisalate (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	Octisalate	5 g in 100 mL
Octocrylene (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	Octocrylene	7 g in 100 mL
Oxybenzone (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	Oxybenzone	4 g in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
Aluminum Starch Octenylsuccinate (UNII: 19 PJO O 6 29 4)				
Benzyl Alcohol (UNII: LKG8494WBH)				
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)				
Dimethicone (UNII: 92RU3N3Y1O)				
EDETATE DISO DIUM (UNII: 7FLD91C86K)				
Methylparaben (UNII: A2I8C7HI9T)				
Polyglyceryl-3 Distearate (UNII: ZI1LK470XV)				
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					
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 N	DC: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)

Revised: 5/2018 Rite Aid