

ULTIMATE SHEER SUNSCREEN SPF 100 RITE AID- avobenzene 3.00% homosalate 15.00% octisalate 5.00% octocrylene 10.00% oxybenzone 6.00% 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.

Drug Facts

Active ingredients	Purpose
Avobenzene - 3.00%	Sunscreen
Homosalate - 15.00%	Sunscreen
Octisalate - 5.00%	Sunscreen
Octocrylene - 10.00%	Sunscreen
Oxybenzone - 6.00%	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 damage 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 the 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
- **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 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 month: Ask a doctor

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Acrylates/Dimethicone Copolymer, Beeswax, BHT, Butyloctyl Salicylate, Chlorphenesin,

Cyclopentasiloxane, Dimethyl Capramide, Dipotassium Glycyrrhizate, Disodium EDTA, Ethylhexylglycerin, Fragrance, Glyceryl Stearate, Methylisothiazolinone, PEG-100 Stearate, Polyester-8, Silica, Styrene/Acrylates Copolymer, Triethanolamine, Water

Other information

- protect this product from excessive heat and direct sun • may stain fabrics.

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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 • may stain fabrics.

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:118 22-1112
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzene (UNII: G63QQF2NOX) (AVOBENZENE - UNII:G63QQF2NOX)	Avobenzene	3 g in 100 mL
Homosalate (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	Homosalate	15 g in 100 mL
Octisalate (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	Octisalate	5 g in 100 mL
Octocrylene (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	Octocrylene	10 g in 100 mL
Oxybenzone (UNII: 95OOS7VE0Y) (OXYBENZENE - UNII:95OOS7VE0Y)	Oxybenzone	6 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
Chlorphenesin (UNII: I670DAL4SZ)	
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)	
Dimethyl Capramide (UNII: O29Y6X2JEZ)	
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
Ethylhexylglycerin (UNII: 147D247K3P)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
Methylisothiazolinone (UNII: 229D0E1QFA)	
PEG-100 Stearate (UNII: YD01N1999R)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TROLAMINE (UNII: 9O3K93S3TK)	
Water (UNII: 059QF0K00R)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)	
METHACRYLATE/METHOXY PEG-10 MALEATE/STYRENE COPOLYMER (UNII: 39DK5WQ2PR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-1112-3	89 mL in 1 TUBE; Type 0: Not a Combination Product	05/25/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/25/2012	

Labeler - Rite Aid (014578892)**Registrant** - Product Quest Mfg (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(11822-1112) , label(11822-1112)

Revised: 10/2017

Rite Aid