## HYDRATING SPF 50- avobenzone 3% homosalate 15% octisalate 5% octocrylene 10% lotion Walgreens

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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#### **Drug Facts**

Active ingredients	Purpose
Avobenzone 3%	Sunscreen
Homosalate 15%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 10%	Sunscreen

**Uses** • helps prevent sunburn • higher SPF gives more sunburn protection • retains SPF after 80 minutes of activity in the water or sweating • provides high protection against sunburn

**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 and as needed. • Children under 6 months of age: ask a doctor. • 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. • For sunscreen use: • apply to all skin exposed to the sun. • reapply as needed or after towel drying, swimming, or sweating.

**Other information** • protect the product in this container from excessive heat and direct sun • may stain fabrics

**Inactive ingredients** Aloe Barbadensis Leaf Extract, Aluminum Starch Octenylsuccinate, Carbomer, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Fragrance, Glycerin, Phenoxyethanol, Polyglyceryl-3 Distearate, Retinyl Palmitate, Sorbitan Isostearate, Sorbitol, Stearic Acid, Tocopherol, Triethanolamine, VP/Eicosene Copolymer, Water.

# Walgreens

# 50 Hydrating

BROAD SPECTRUM SPF 50 SUNSCREEN UVA/UVB

HYPOALLERGENIC

**OXYBENZONE FREE** 

PARABEN FREE

- Oil free
- Water resistant (80 minutes)



8 FL 0Z (236 mL)

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#### 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 or irritation develops and lasts.

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

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#### Questions? 1-800-925-4733



Health expertise you rely on, quality you trust.



Walgreens Pharmacist Survey

#### Questions or comments? 1-800-925-4733

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ORG0717-F-R2

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avobenzone 3% homosalate 15% octisalate 5% octocrylene 10% lotion

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-1121
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Route of Administration TOPICAL

#### Active Ingredient/Active Majety

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Ingredient Name	Basis of Strength	Strength
Avobenzone (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	Avobenzone	3 g in 100 mL

3-248PO

Homosalate (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	Ho mo sa la te	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

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
Aluminum Starch Octenylsuccinate (UNII: 19PJ0O6294)		
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)		
Dimethicone (UNII: 92RU3N3Y1O)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
Ethylhexylglycerin (UNII: 147D247K3P)		
Glycerin (UNII: PDC6A3C0OX)		
Phenoxyethanol (UNII: HIE492ZZ3T)		
Polyglyceryl-3 Distearate (UNII: ZI1LK470XV)		
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)		
Sorbitan Isostearate (UNII: 01S2G2C1E4)		
Sorbitol (UNII: 506T60A25R)		
Stearic Acid (UNII: 4ELV7Z65AP)		
Tocopherol (UNII: R0 ZB2556 P8)		
TROLAMINE (UNII: 9O3K93S3TK)		
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)		
water (UNII: 059QF0KO0R)		

F	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1	NDC:0363-1121-06	236 mL in 1 CAN; Type 0: Not a Combination Product	11/16/2016		
2	NDC:0363-1121-07	296 mL in 1 TUBE; Type 0: Not a Combination Product	11/16/2016		
3	NDC:0363-1121-03	89 mL in 1 TUBE; Type 0: Not a Combination Product	11/16/2016		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/16/2016	

### Labeler - Walgreens (008965063)

## Registrant - Product Quiest Mfg (927768135)

Establishment			
Name	Address	ID/FEI	Business Operations
Product Quiest Mfg		927768135	manufacture(0363-1121), label(0363-1121)

Revised: 5/2018 Walgreens