# HYDRATING SPF 50- avobenzone 3.00% homosalate 15.00% octisalate 5.00% octocrylene 10.00% spray 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 moderate protection against sunburn

#### Warnings

**Flammable**: Do not use near heat, flame, or while smoking. **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 last

Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F.

**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. • Hold container 4 to 6 inches from the skin to apply. • Do not spray directly into face. Spray on hands then apply to face. • Do not apply in windy conditions. • Use in a well-ventilated area. • For sunscreen use: • apply to all skin exposed to the sun. • Reapply as needed or after towel drying, swimming, or sweating.

## **Inactive Ingredients:**

Acrylates/Octylacrylamide Copolymer Alcohol Denat. Aloe Barbadensis Leaf Extract Caprylic/Capric Triglyceride Diethylhexyl Syringylidenemalonate Fragrance Glycerin Retinyl Palmitate Stearoxytrimethylsilane Tocopherol



## **HYDRATING SPF 50**

avobenzone 3.00% homosalate 15.00% octisalate 5.00% octocrylene 10.00% spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-1120
Route of Administration	TOPICAL		

	/Active Moiety					
	Ingredient Name		Basis of Stre	ngth Stre	ngth	
Avobenzone (UNII: G63	BQQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX	.)	Avobenzone	3 g in 1	l00 g	
HOMOSALATE (UNII:	V06SV4M95S)(HOMOSALATE - UNII:V06SV4M95	S)	HOMOSALATE	15 g in	100 g	
Octisalate (UNII: 4X49	Y0596W) (OCTISALATE - UNII:4X49Y0596W)		Octisalate	5 g in 1	l00 g	
Octocrylene (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) Octocrylene				10 g in	100 g	
Inactive Ingredie						
	Ingredient Name			Streng	gth	
ALCOHOL (UNII: 3K99	958 V90 M)					
ALOE VERA LEAF (UN	NII: ZY8 1Z8 3H0 X)					
MEDIUM-CHAIN TRIG	LYCERIDES (UNII: C9H2L21V7U)					
Diethylhexyl Syringyli	denemalonate (UNII: 3V5U97P248)					
Glycerin (UNII: PDC6A	3C0OX)					
VITAMIN A PALMITA	<b>ΓΕ</b> (UNII: 1D1K0N0VVC)					
Stearoxytrimethylsilane (UNII: 9862TW94B2)						
Tocopherol (UNII: R0Z	B2556P8)					
Packaging						
# Item Code	Package Description	Marke	eting Start Date	Marketing En	d Dat	
<b>1</b> NDC:0363-1120-05	156 g in 1 CAN; Type 0: Not a Combination Produc	11/16/20	16			
<b>2</b> NDC:0363-1120-06	283 g in 1 CAN; Type 0: Not a Combination Produc	t 11/16/20	11/16/2016			
	ormation					
Marketing Info						
Marketing Info	y Application Number or Monograph Cita	tion Mar	keting Start Date	Marketing En	d Dat	

# Labeler - Walgreens (008965063)

# **Registrant -** Product Quest Mfg (927768135)

## Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(0363-1120) , label(0363-1120)

Revised: 4/2018

Walgreens