# HYDRATING PROTECTION SUNSCREEN CVS- avobenzone 3.0% homosalate 15.0% octisalate 5.0% octocrylene 10.0% oxybenzone 6.0% lotion CVS

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
Oxybenzone 6%	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**

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Acrylates/Dimethicone Copolymer, Adipic Acid/Diglycol Crosspolymer, Avena Sativa (Oat) Kernel Extract, Avena Sativa (Oat) Kernel Flour, Beeswax, BHT, Bisabolol, Cyclopentasiloxane, Dipotassium Glycyrrhizate, Disodium EDTA, Ethylhexylglycerin, Fragrance, Glycerin, Glyceryl Stearate, Hydrated Silica, Hydrolyzed Oat Protein, PEG-100 Stearate, Phenoxyethanol, Polyester-8, Potassium Palmitoyl Hydrolyzed Oat Protein, Styrene/Acrylates Copolymer, Triethanolamine, Water



#### HYDRATING PROTECTION SUNSCREEN CVS

avobenzone 3.0% homosalate 15.0% octisalate 5.0% octocrylene 10.0% oxybenzone 6.0% lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-054	
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	15 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	10 g in 100 mL	
Oxybenzone (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	Oxybenzone	6 g in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ADIPIC ACID/DIGLYCOL CROSSPOLYMER (20000 MPA.S) (UNII: R9TPS68K19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)	
LEVOMENOL (UNII: 24WE03BX2T)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Glycerin (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)	
Hydrated Silica (UNII: Y6O7T4G8P9)	
PEG-100 Stearate (UNII: YD01N1999R)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
POLYESTER-8 (1400 MW, CYANO DIPHENYLPRO PENO YL CAPPED) (UNII: T9296U138P)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
OAT (UNII: Z6J799EAJK)	
OATMEAL (UNII: 8PI54V663Y)	

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:69842-054-03	$88\ mL$ in $1\ PACKAGE;$ Type $0\colon Not\ a\ Combination\ Product$	02/16/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/16/2017	

# **Labeler -** CVS (062312574)

Registrant - Product Quest Mfg. (927768135)

## Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg.		927768135	manufacture(69842-054)

Revised: 12/2017 CVS