QC SPF 30 SUNSCREEN- avobenzone 3%, homosalate 15%, octisalate 5%, octocrylene 6% lotion CDMA

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.

QC SPF 30 Sunscreen Lotion

Active Ingredients

Avobenzone 3%, Homosalate 15%, Octisalate 5%, Octocrylene 6%

Purpose

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 damaged or broken skin. **When using this product** keep out of eyes. Rinse eyes with water to remove.

Stop use and ask a doctor if rash occurs.

Keep Out of Reach of 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 n the sun increases your risk of skin cancer and early skin aging. To decrease risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measure including:

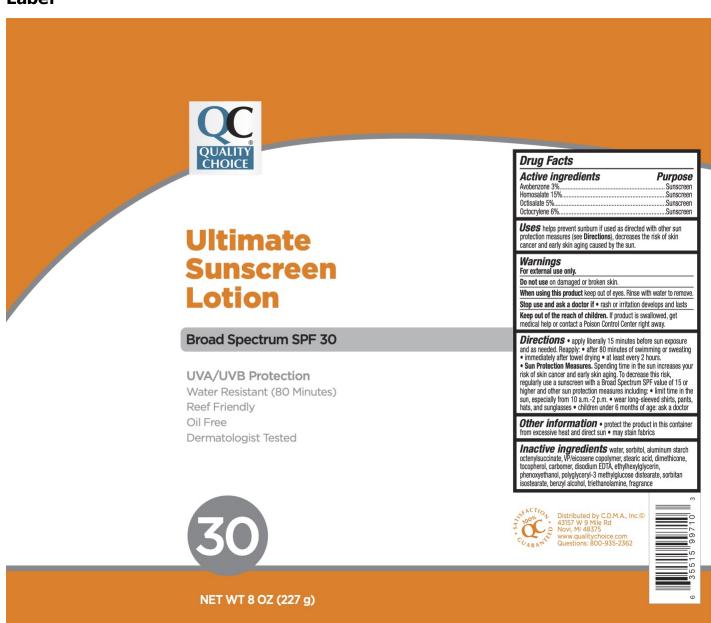
• limit time in the sun, especially from 10 am to 2 pm

- wear long-sleeved shirts, pants, hats, and sunglasses.
- Children under 6 months: ask a doctor.

Inactive Ingredients

Water, sorbitol, aluminum starch octenylsuccinate, VP/eicosene copolymer, stearic acid, dimethicone, tocopherol, carbomer, disodium EDTA, ethylhexylglycerin, phenoxyethanol, polyglyceryl-3 methylglucose distearate, sorbitan isostearate, benzyl alcohol, triethanolamine, fragrance.

Label



QC SPF 30 SUNSCREEN

avobenzone 3%, homosalate 15%, octisalate 5%, octocrylene 6% lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-913
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 g	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	6 g in 100 g	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 g in 100 g	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ0O6294)	
TOCOPHEROL (UNII: R0ZB2556P8)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-3 METHYLGLUCOSE DISTEARATE (UNII: W19EIOODBE)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 903K93S3TK)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	
CARBOMER 940 (UNII: 4Q93RCW27E)	

Packaging				
# Item	Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:63		227 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/22/2021	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	12/22/2021		

Labeler - CDMA (011920774)

Registrant - Derma Care Research Labs, LLC (116817470)

Establishment				
Name	Address	ID/FEI	Business Operations	
Derma Care Research Labs		116817470	manufacture(63868-913)	

Revised: 3/2023 CDMA