

**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 in 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



Ultimate Sunscreen Lotion

Broad Spectrum SPF 30

UVA/UVB Protection
Water Resistant (80 Minutes)
Reef Friendly
Oil Free
Dermatologist Tested

30

NET WT 8 OZ (227 g)

Drug Facts

Active ingredients	Purpose
Avobenzone 3%.....	Sunscreen
Homosalate 15%.....	Sunscreen
Octisalate 5%.....	Sunscreen
Octocrylene 6%.....	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 with water to remove.
Stop use and ask a doctor if • rash or irritation develops and lasts
Keep out of the 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. 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 • children under 6 months of age: ask a doctor

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

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

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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: I9PJ006294)	
TOCOPHEROL (UNII: R0ZB2556P8)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-3 METHYLGLUCOSE DISTEARATE (UNII: W19EIO0DBE)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
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:63868-913-08	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