

DERMATONE SUNSCREEN SPF 30- avobenzene 3.00% homosalate 10.00% octisalate 5.00% octocrylene 10.00% lotion

Beaumont Products

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.

Drug Facts

Active ingredient

Avobenzene - 3.00%
Homosalate - 10.00%
Octisalate - 5.00%
Octocrylene - 10.00%

Purpose

Sunscreen

Uses

Uses • helps prevent sunburn • if used as directed with other sun protection measures (see Direction) decreases the risk of skin cancer

Warning 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 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

Other Information

protect this product from excessive heat and direct sun

Inactive Ingredients:

Acrylates/C10-30 Alkyl Acrylate Crosspolymer

Benzyl Alcohol

Caprylic/Capric Triglyceride

Chlorphenesin

Diethylhexyl Syringylidenemalonate

Disodium EDTA

Ethylhexyl Palmitate

Oleth-3

Polyamide-8

Sodium Ascorbyl Phosphate

Sorbitol

Tocopherol

Triethanolamine

Water

FRAGRANCE FREE
SPF 30

Official Sunscreen Of



DERMATONE[®]
 Sunscreen Lotion

Fragrance Free

Water Resistant
 (80 Minutes)

Broad Spectrum SPF 30

Moisturizing

Non-Greasy

1 FL. OZ. (30mL)

Drug Facts

Active Ingredient Purpose

Avobenzone 3.0%	}	Sunscreen
Homosalate 10.0%		
Octisalate 5.0%		
Octocrylene 10.0%		

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 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 and 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

Other Information • Protect this product from excessive heat and direct sun.

Inactive ingredients Water, Sorbitol, Ethylhexyl Palmitate, Polyamide-8, Tocopherol, Sodium Ascorbyl Phosphate, Oleth-3, Benzyl Alcohol, Caprylic/Capric Triglyceride, Triethanolamine, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Chlorphenesin, Diethylhexyl Syringyldenemalonate, Disodium EDTA.

Distributed By:
 Beaumont Products, Inc.
 Kennesaw, GA 30144

Questions or Comments
 1-800-451-7096
 dermatone.com
 facebook.com/dermatone



Made in the USA
 with US and
 imported materials



DR35090 /
 REV 0117

DERMATONE SUNSCREEN SPF 30

avobenzone 3.00% homosalate 10.00% octisalate 5.00% octocrylene 10.00% lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:65449-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzon e (UNII: G63QQF2NOX) (AVOBENZON - UNII:G63QQF2NOX)	Avobenzon	3 g in 100 mL
Homosalat e (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	Homosalat	10 g in 100 mL
Octisalate (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	Octisalate	5 g in 100 mL
Octocrylen e (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	Octocrylen	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
Benzyl Alcohol (UNII: LKG8494WBH)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
Chlorphenesin (UNII: I670DAL4SZ)	
Diethylhexyl Syngylidenemalonate (UNII: 3V5U97P248)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
Ethylhexyl Palmitate (UNII: 2865993309)	
Oleth-3 (UNII: BQZ26235UC)	
Sodium Ascorbyl Phosphate (UNII: 836SJK51DR)	
Sorbitol (UNII: 506T60A25R)	
Tocopherol (UNII: R0ZB2556P8)	
TROLAMINE (UNII: 9O3K93S3TK)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65449-001-01	30 mL in 1 TUBE; Type 0: Not a Combination Product	12/27/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/27/2016	

Labeler - Beaumont Products (120935804)

Registrant - Product Quest Mfg (120935804)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		120935804	manufacture(65449-001) , label(65449-001)