

PAULAS CHOICE BROAD SPECTRUM SPF 50- avobenzene, octinoxate, octisalate, octocrylene lotion
Prime Enterprises

Paula's Choice SPF 50 Broad Spectrum 5% Vitamin C Sheer Moisturizer

Active Ingredients

Avobenzene 2%

Octinoxate 7.5%

Octisalate 5%

Octocrylene 2%

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

When using this product

keep out of eyes. Rinse with water to remove

Do not use

on damaged or broken skin

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

- SHAKE WELL. Apply liberally 15 minutes before sun exposure
- Use a water-resistant sunscreen if swimming or sweating
- Reapply:

- immediately after towel drying
- at least every two hours
- children under 6 months of age: ask a doctor
- 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 am - 2 pm
- wear long-sleeve shirts, pants, hats and sunglasses

Other Information

protect the product in this container from excessive heat and direct sun. Store at 20 - 25 °C (68 - 77 °F)

Inactive Ingredients

Water, Glycerin, Silica, 3-O-Ethyl Ascorbic Acid, Ascorbyl Glucoside, Dimethicone, Propanediol, Tetrahexyldecyl Ascorbate, Acetyl Zingerone, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Diethylhexyl Syringylidenemalonate, Dimethicone/Vinyl Dimethicone Crosspolymer, Entada Phaseoloides Bark/Seed Extract, Porphyra Umbilicalis Extract, Hydrogenated Lecithin, Ricinus Communis (Castor) Seed Oil, Sodium Hydroxide, Tocopherol, Xanthan Gum, Ethylhexylglycerin, Laureth-4, Phenoxyethanol, Potassium Sorbate, Sodium Benzoate, Titanium Dioxide, Iron Oxides (CI 77492), Iron Oxides (CI 77491), Iron Oxides (CI 77499)

Questions or Comments?

Call 1.800.831.4088 (U.S. and Canada) Mon-Fri 6 am - 6 pm PT | Sat-Sun 8 am - 4:30 pm PT

PAULA'S CHOICE

SPF 50

Broad Spectrum

5% Vitamin C Sheer Moisturizer

WITH ALGAE AMINOS

All Skin Types

✓ BRIGHTENS DULLNESS & HELPS PREVENT DARK SPOTS

✓ WEIGHTLESS, INVISIBLE HYDRATION

60 ml / 2 fl. oz.

5

MOISTURIZE | AM

Drug Facts

Active Ingredients	Purpose
Avobenzone 2.0%	Sunscreen
Octinoxate 7.5%	Sunscreen
Octisalate 5.0%	Sunscreen
Octocrylene 2.0%	Sunscreen

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Inactive Ingredients: Water, Glycerin, Silica, 3-O-Ethyl Ascorbic Acid, Ascorbyl Glucoside, Dimethicone, Propenediol, Tetrahydroxyl Ascorbate, Acetyl Zingiberone, Acrylate/C10–30 Alkyl Acrylate Copolymer, Diethylhexyl Syringylidenemalonate, Dimethicone/Vinyl Dimethicone Copolymer, Ethylhexyl Triethoxycarbonyl Benzoate, Porphyrin, Umbelliferone Extract, Hydrogenated Lecithin, Ricinus Communis (Castor) Seed Oil, Sodium Hydroxide, Tocopherol, Xanthan Gum, Ethylhexylglycerin, Laureth-4, Phenoxyethanol, Potassium Sorbate, Sodium Benzoate, Titanium Dioxide, Iron Oxides (CI 77489), Iron Oxide (CI 77491), Iron Oxide (CI 77492). [r1/08b2v2]

Questions or Comments? Call 1.800.831.4088 (U.S. and Canada) Mon–Fri 9 AM–6 PM PT | Sat–Sun 9 AM–4:30 PM PT

Manufactured in the USA for Paula's Choice, LLC, Seattle, WA 98104. Distributed in Europe by Paula's Choice Europe B.V., Amerfoort, NL, London, UK.

1.800.831.4088 (U.S. and Canada)
PaulasChoice.com



PAULAS CHOICE BROAD SPECTRUM SPF 50

avobenzone, octinoxate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0660
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	21 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	78.75 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	52.5 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	21 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
RICINUS COMMUNIS SEED (UNII: 7EK45FN1TX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LAURETH-4 (UNII: 6HQ855798J)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
ACETYL ZINGERONE (UNII: V9D92S9YE5)	
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	
ENTADA PHASEOLOIDES SEED (UNII: 4R80X8KTM7)	
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PROPANEDIOL (UNII: 5965N8W85T)	
ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER (60000 MPA.S) (UNII: 8Z5ZAL5H3V)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ASCORBYL GLUCOSIDE (UNII: 2V52R0NHXW)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
WATER (UNII: 059QF0KO0R)	
3-O-ETHYL ASCORBIC ACID (UNII: 6MW60CB71P)	

Product Characteristics

Color	brown (Nude/Peach)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0660-3	60 mL in 1 TUBE; Type 0: Not a Combination Product	05/17/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/17/2024	

Labeler - Prime Enterprises (101946028)

Registrant - Prime Enterprises (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises		101946028	analysis(58443-0660) , label(58443-0660) , manufacture(58443-0660) , pack(58443-0660)

Revised: 5/2024

Prime Enterprises