

**SKIN BALANCING ULTRA SHEER DAILY DEFENCE SPF 30 PAULAS CHOICE-
avobenzone, homosalate, octocrylene, oxybenzone cream
Cosmetic Enterprises Ltd**

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.

Skin Balancing Broad Spectrum SPF 30

Active Ingredients	Purpose
Avobenzone 3.0%	Sunscreen
Homosalate 7.0%	Sunscreen
Octocrylene 2.0%	Sunscreen
Oxybenzone 4.0%	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 sun.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if rash occurs

Warnings

For external use only.

When using this product keep out of eyes. Rinse with water to remove.

Directions

- Apply liberally 15 minutes before sun exposure
- Use a water-resistant sunscreen if swimming or sweating:
- 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 10AM - 2PM
- Wear long-sleeve shirts, pants, hats and sunglasses

Water (Aqua), Butylene Glycol, Silica, Aluminum Starch Octenylsuccinate, Cetyl Dimethicone, Camelia Sinensis (Green Tea) Leaf Extract, Aloe Barbadosensis Leaf Juice Powder, Ascorbyl Palmitate, Phospholipids, Superoxide Dismutase, Adenosine, Tocopherol, Bisabolol, Boerhavia Diffusa Root Extract, Colloidal Oatmeal, Panthenol, Ginkgo Biloba Leaf Extract, Salix Alba (Willow) Bark Extract, Acrylate/C10-30 Alkyl Acrylate Crosspolymer, Titanium Dioxide, Sodium Hydroxide, Steareth-21, Steareth-2, Polysorbate 20, Disodium EDTA, Phenoxyethanol, Sorbic Acid

Paula's Choice

Skin Balancing Ultra-Sheer Daily Defense

Broad Spectrum SPF 30

60ml / 2 fl. oz.

PAULA'S CHOICE

SKIN BALANCING

ULTRA-SHEER DAILY DEFENSE

Broad Spectrum SPF 30

Normal • Oily • Combination

with Antioxidants

What it does:

- + Hydrates without adding shine
- + Prevents signs of aging
- + Helps protect skin from sun damage

Our products are
non-irritating, fragrance free
and never animal tested.

Paula Begoun

moisturizer + spf

60 ml / 2 fl. oz.

Drug Facts

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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 (Aqua), Butylene Glycol, Silica, Aluminum Starch Octylsuccinate, Cetyl Dimethicone, Camellia Sinensis (Green Tea) Leaf Extract, Aloe Barbadosensis Leaf Juice Powder, Ascorbyl Palmitate, Phospholipids, Superoxide Dismutase, Adenosine, Tocopherol, Bisabolol, Boerhavia Diffusa Root Extract, Colloidal Oatmeal, Panthenol, Ginkgo Biloba Leaf Extract, Salix Alba (Willow) Bark Extract, Acrylate/C10-30 Alkyl Acrylate Crosspolymer, Titanium Dioxide, Sodium Hydroxide, Steareth-21, Steareth-2, Polysorbate 20, Disodium EDTA, Phenoxyethanol, Sorbic Acid. [r316/i116v1]

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

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1.800.831.4088
(U.S. and Canada)

PaulasChoice.com



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avobenzone, homosalate, octocrylene, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56152-5001
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	7 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SUPEROXIDE DISMUTASE (SACCHAROMYCES CEREVISIAE) (UNII: W2T4YRA9AD)	
ADENOSINE (UNII: K72T3FS567)	
TOCOPHEROL (UNII: R0ZB2556P8)	
LEVOMENOL (UNII: 24WE03BX2T)	
BOERHAVIA DIFFUSA ROOT (UNII: KR0SR09KYL)	
OATMEAL (UNII: 8PI54V663Y)	
PANTHENOL (UNII: WV9CM0O67Z)	
GINKGO (UNII: 19FUJ2C58T)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARETH-21 (UNII: 53J3F32P58)	
STEARETH-2 (UNII: V56DFE46J5)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SORBIC ACID (UNII: X045WJ989B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:56 152-500 1-1	1.5 mL in 1 PACKET; Type 0: Not a Combination Product	08/12/2016	
2	NDC:56 152-500 1-2	60 mL in 1 TUBE; Type 0: Not a Combination Product	08/12/2016	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part352		08/12/2016	

Labeler - Cosmetic Enterprises Ltd (017701475)

Registrant - Cosmetic Enterprises Ltd (017701475)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Enterprises Ltd		017701475	manufacture(56152-5001)

Revised: 1/2017

Cosmetic Enterprises Ltd