

ETERNAL SPIRIT BEAUTY SPF 50 SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene, and oxybenzone spray

Prime Enterprises Inc.

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.

Eternal beauty Sunscreen Spray SPF 50 Broad Spectrum

Active ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 2.75%

Oxybenzone 4%

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 with water to remove. Keep away from face to avoid breathing it.

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.

Flammable: Do not use near heat, flame or while smoking.

Directions:

- shake well
- close eyes completely. Mist over face evenly, holding bottle 10-12 inches away from face. Do not breathe mist in. Wait until dry.
- apply liberally and evenly 15 minutes before sun exposure.
- do not apply in windy conditions.
- use in a well ventilated area
- 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 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

Inactive ingredients:

SD Alcohol 40-B, Cyclopentasiloxane, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Water, Silica Silylate, Rosa Damascena Flower Water, Mentha Viridis (Spearmint) Leaf Oil, Bisabolol, Polyester-8, Tocopheryl Acetate, Ascorbyl Palmitate, Glycerin, Camellia Oleifera (Green Tea) Leaf Extract, Benzyl Alcohol, Aloe Barbadensis Leaf Juice Powder, Dehydroacetic Acid, Sodium Hyaluronate.

Other Information:

- protect this product from excessive heat and direct sun
- avoid spraying on fabrics - could cause discoloration

Question or comments?

Call 1-866-983-8582

Eternal Spirit Beauty Sunscreen Spray SPF 50



SUNSCREEN SPRAY 50 Face Setting Spray



Broad Spectrum SPF 50
Water Resistant (80 Minutes)

4 FL OZ / 118.2 mL

Drug Facts

Active Ingredients

Avobenzone 3%, Homosalate 10%, Octisalate 5%,
Octocrylene 2.75%, Oxybenzone 4% } Sunscreen

Purpose

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. Keep away from face to avoid breathing it. • 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. • Flammable: Do not use near heat, flame or while smoking.

Directions:

• shake well • close eyes completely. Mist over face evenly, holding bottle 10-12 inches away from face. Do not breathe mist in. Wait until dry. • apply liberally and evenly 15 minutes before sun exposure. • do not apply in windy conditions. • use in a well-ventilated area • 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 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.

Inactive Ingredients:

Alcohol Denat, Cyclopentasiloxane, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Water, Silica Silylate, Rosa Damascena Flower Water, Mentha Viridis (Spearmint) Leaf Oil, Bisabolol, Polyester-8, Tocopheryl Acetate, Ascorbyl Palmitate, Glycerin, Camellia Oleifera (Green Tea) Leaf Extract, Benzyl Alcohol, Aloe Barbadensis Leaf Juice, Dehydroacetic Acid, Sodium Hyaluronate.

Other Information:

• protect this product from excessive heat and direct sun
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Questions and comments:

Call +1 (305)468-8270

FREE OF PARABENS & SULFATES

DISTRIBUTED BY: WORLDWIDE COSMETICS INC.
2011 NW 84 AVE DORAL, FL 33122
MADE IN USA - FROM US AND IMPORTED INGREDIENTS

ETERNAL SPIRIT BEAUTY SPF 50 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0339
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	26.4 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	88 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	44 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	24.2 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	35.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
SPEARMINT OIL (UNII: C3M81465G5)	
ROSA DAMASCENA FLOWER OIL (UNII: 18920M3T13)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSPOG0W)	
WATER (UNII: 059QF0K00R)	
ISOBORNYL ACRYLATE (UNII: IX0PRH184P)	
ALCOHOL (UNII: 3K9958V90M)	
LEVOMENOL (UNII: 24WE03BX2T)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Product Characteristics

Color	yellow (Very light yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0339-3	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/11/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/11/2018	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc		101946028	manufacture(58443-0339) , analysis(58443-0339) , pack(58443-0339) , label(58443-0339)

