ULTA BEAUTY BROAD SPECTRUM SPF 50 SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene, and oxybenzone lotion
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.

Ulta Beauty MAKEUP SETTING SPRAY SPF 50 Broad Spectrum Sunscreen

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.

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 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 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

Alcohol Denat, Aloe Barbadensis Leaf Juice, Ascorbyl Palmitate, Benzimidazole Diamond Amidoethyl Urea Carbamoyl Propyl Polymethylsilsesquioxane, Benzyl Alcohol, Bisabolol, Camellia Oleifera (Green Tea) Leaf Extract, Cyclopentasiloxane, Dehydroacetic Acid, Fragrance, Glycerin, Polyester-8, Rosa Damascena Flower Water, Silica Silylate, Sodium Hyaluronate, Tocopheryl Acetate, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Water

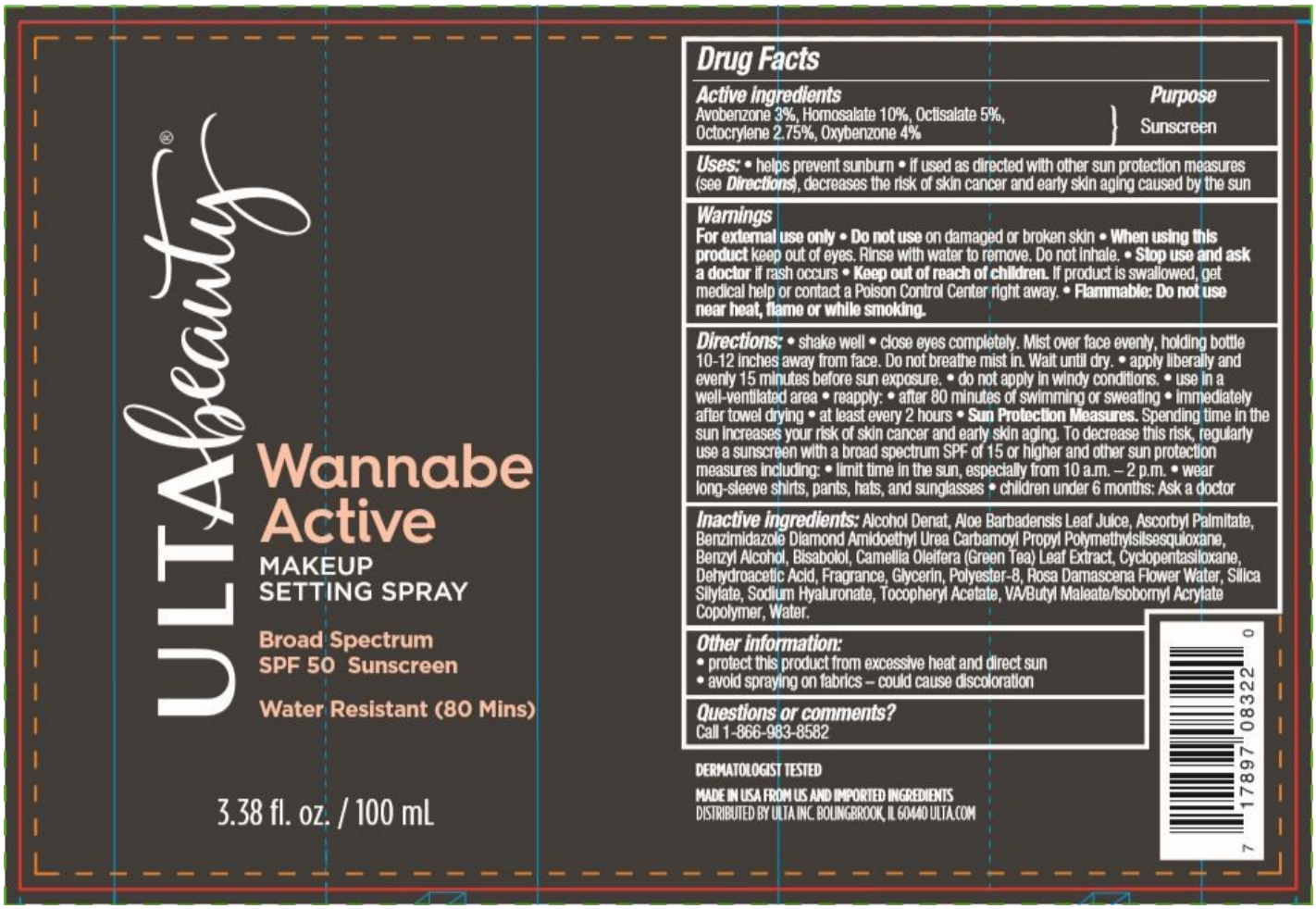
Other Information

- protect this product from excessive heat and direct sun
- avoid contact with fabrics - could cause discoloration

Question or comments?

Call 1-866-983-8582

Ulta Beauty SPF 50 Broad Spectrum Sunscreen



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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0323
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	46.45 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	37.16 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	25.55 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	27.87 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	92.9 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIBUTYL MALEATE (UNII: 4X371TMK9K)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ALCOHOL (UNII: 3K9958V90M)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
MIDAMALINE HYDROCHLORIDE (UNII: 4CVP92LH8L)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
ROSA DAMASCENA FLOWER OIL (UNII: 18920M3T13)	
LEVOMENOL (UNII: 24WE03BX2T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0323-3	100 mL in 1 TUBE; Type 0: Not a Combination Product	03/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/04/2020	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0323) , manufacture(58443-0323) , label(58443-0323) , analysis(58443-0323)

Revised: 5/2020 Prime Enterprises Inc.