ULTA BROAD SPECTRUM SPF 15- avobenzone, octisalate and octocrylene spray
Prime Packaging, 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.

Active ingredients

Avobenzone 2 %, Octisalate 5 %, Octocrylene 1.85 %

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 broken or damaged skin

When using this product keep out of eyes. Rinse with water to remove.
- keep away from face to avoid breathing it
- contents under pressure - do not puncture or incinirate. Do not store at temperatures above 120 ^{0}F

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
- spray liberally and spread evenly by hand 15 minutes before sun exposure
- hold container 4 to 6 inches from the skin to apply
- do not spray directly into face. Spray on hands then apply to face
- do not apply in windy conditions
- use in well-ventilated areas
- 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

Inactive Ingredients

Aloe Barbadensis Leaf Juice, Diethylhexyl 2,6-Naphthalate, Fragrance (Parfum), Polyester-8, SD Alcohol 40-B (Alcohol Denat.), VA/Butyl Maleate/Isobornyl Acrylate Copolymer

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

Questions or Comments?

Call toll free 1-866-983-8582

PRINCIPAL DISPLAY PANEL - 177 mL Can Label

Drug Facts

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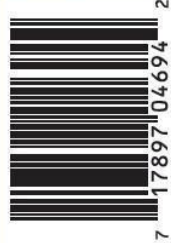
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MADE IN USA
FROM US AND IMPORTED
INGREDIENTS
DISTRIBUTED BY ULTA
BOLINGBROOK, IL 60440
www.ulta.com

7 17897 04694 2

SUNCARE
BROAD SPECTRUM SPF 15

WATER RESISTANT
(80 MINUTES)
OIL–FREE
CONTINUOUS SPRAY SUNSCREEN

ULTA

6 fl oz/177 ml

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BROAD

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ULTA

6 Fl. Oz/177 mL

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avobenzone, octisalate and octocrylene spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0068
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	16.2 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	14.9 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	40.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
ALCOHOL (UNII: 3K9958V90M)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0068-4	177 mL in 1 CAN; Type 0: Not a Combination Product	12/17/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/17/2013	

Labeler - Prime Packaging, Inc. (805987059)

Registrant - Prime Packaging, Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0068) , analysis(13630-0068)

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Prime Packaging, Inc.		805987059	label(13630-0068) , pack(13630-0068)

Revised: 1/2020   Prime Packaging, Inc.