# ULTIMATE SHEER SPF 55 BODY- avobenzone 3.00% homosalate 15.00% octisalate 5.00% octocrylene 2.75% oxybenzone 6.00% spray TopCo

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.

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## **Drug Facts**

Active ingredients Purpose Avobenzone 3.00%, Homosalate 15.00%, Octisalate 5.00%, Octocrylene 2.75%, Oxybenzone 6.00%.

Sunscreen

 $Uses \cdot helps prevent sunburn$ 

### Warnings

For external use only

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

Do not use on damaged or broken skin

**When using this product** • Keep out of eyes. Rinse eyes with water to remove. • Keep away from face to avoid breathing it • Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°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.

#### **Directions**

- spray liberally and spread evenly by hand 15 minutes before sun exposure
- reapply: after 80 minutes of swimming or sweating
- immediately after towel drying at least every 2 hours
- 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 a well-ventilated area
- **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**

Acrylates Dimethicone Copolymer, Acrylates/Octylacrylamide Copolymer, Alcohol Denat., Ascorbyl Palmitate, Cyclopentasiloxane, Dimethicone, Fragrance, Polyester-8, PPG-5-Ceteth-20, Retinyl Palmitate, Tocopheryl Acetate, Trisiloxane.

**Other information** • protect this product from excessive heat and direct sun • may stain fabrics



#### ULTIMATE SHEER SPF 55 BODY

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-722
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 g	
Homosalate (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	Homosalate	15 g in 100 g	
Octisalate (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	Octisalate	5 g in 100 g	
Octocrylene (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	Octocrylene	2.75 g in 100 g	
Oxybenzone (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	Oxybenzone	6 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
Alcohol (UNII: 3K9958V90M)			
Ascorbyl Palmitate (UNII: QN83US2B0N)			
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)			
Dimethicone (UNII: 92RU3N3Y1O)			
POLYESTER-8 (1400 MW, CYANO DIPHENYLPRO PENO YL CAPPED) (UNII: T9296U138P)			
PPG-5-Ceteth-20 (UNII: 4AAN25P8P4)			
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)			
.ALPHATO CO PHERO L ACETATE (UNII: 9E8X80D2L0)			
Trisiloxane (UNII: 9G1ZW13R0G)			

Packaging				
l	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
l	1 NDC:36800-722-04	141 g in 1 CAN; Type 0: Not a Combination Product	12/13/20 12	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/13/20 12	

# **Labeler -** TopCo (006935977)

# Registrant - Product Quest Mfg (927768135)

Establishment			
Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(36800-722), label(36800-722)

Revised: 7/2018 TopCo