BU SPF 30 BROAD SPECTRUM ON ALCOHOL-FREE PERFORMANCE SUNSCREEN - FRAGRANCE FREE- octinoxate, octocrylene, octisalate, and avobenzone spray Bu Brands, LLC

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.

bü SPF 30 Broad Spectrum Spray on Alcohol-Free Performance Sunscreen - Fragrance Free Drug Facts

Active Ingredients

Octinoxate (7.500%) Octocrylene (7.500%) Octisalate (5.00%) Avobenzone (2.500%)

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.

Do not use near flame or while smoking

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
- Do not spray directly onto the face. Spray into hands, and apply to the face.

- children under 6 months: 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 10 a.m. -2 p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses

Inactive Ingredients

Cyclopentasiloxane, Butyloctyl Salicylate, Ethylhexyl Methoxycrylene, Diphenylsiloxy Phenyl Trimethicone, VP/Hexadecene Copolymer, Polybutene, Octyldodecanol, Tocopherols, Bisabolol.

Other Information

• protect this product from excessive heat and direct sun

Questions or Comments?

Call: 310-456-8787 www.goodtobebu.com

Manufactured by **Cosmaceuticals**, Surrey, BC, V3W 1K7

PRINCIPAL DISPLAY PANEL - 98 mL Bottle Label

SPF30 broad spectrum

spray-on alcohol-free performance sunscreen

Oil-Free Preservative-Free with Antioxidants Fragrance-Free bü

Water Resistant (80 Minutes)

3.3oz (98mL)





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sunscreen

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with Antioxidants Fragrance-Free



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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:70325-3001

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7.5 g in 100 mL	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 g in 100 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.5 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)		
ETHYLHEXYL PALMITATE (UNII: 2865993309)		
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)		
DIPHENYLSILO XY PHENYL TRIMETHICO NE (UNII: 1445L28B12)		
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)		
TOCOPHEROL (UNII: R0 ZB2556 P8)		
.ALPHABISABOLOL, (+/-)- (UNII: 36 HQN158 VC)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70325-3001- 3	98 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	12/0 1/20 16	
2	NDC:70325-3001- 1	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/0 1/20 16	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH NOT FINAL	part352	12/0 1/20 16			

Labeler - Bu Brands, LLC (080075929)

Establishment				
Name	Address	ID/FEI	Business Operations	
Westwood Laboratories, Inc.		069926483	MANUFACTURE(70325-3001)	

Revised: 2/2017 Bu Brands, LLC