# 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.

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## 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)





spray-on alcohol-free performance

### sunscreen

Oil-Free Preservative-Free

with Antioxidants Fragrance-Free



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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70325-3001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	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: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	2.5 g in 100 mL	

Inactive Ingredients				
Ingredient Name	Strength			
CYCLOMETHICONE 5 (UNII: OTHT5PCIOR)				
ETHYLHEXYL PALMITATE (UNII: 2865993309)				
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)				
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: 1445L28B12)				
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)				
TOCOPHEROL (UNII: ROZB2556P8)				
.ALPHABISABOLOL, (+/-)- (UNII: 36HQN158VC)				

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	12/01/2016	
2	NDC:70325- 3001-1	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/01/2016	
FINAL	part352	12/01/2016	

## Labeler - Bu Brands, LLC (080075929)

Establishment				
Name	Address	ID/FEI	Business Operations	
Westwood Laboratories, Inc.		832280635	MANUFACTURE(70325-3001) , LABEL(70325-3001)	

Revised: 12/2022 Bu Brands, LLC