BU SPF 50 KIDS BROAD SPECTRUM ALCOHOL-FREE PERFORMANCE SUNSCREEN - FRAGRANCE FREE- octinoxate, octocrylene, octisalate, avobenzone, and homosalate 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 50 KIDS Broad Spectrum Spray on Alcohol-Free Performance Sunscreen - Fragrance Free

Drug Facts

Active Ingredients

Octocrylene 10.00% Octinoxate 7.50% Homosalate 7.50% Octisalate 5.00% Avobenzone 3.00%

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 (and) Octyldodecanol, Polybutene, Tocopherols, Bisabolol.

Other Information

• protect this product from excessive heat and direct sun

Questions or Comments?

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

PRINCIPAL DISPLAY PANEL - 98 mL Bottle Label

SPF50

broad spectrum

KiDS

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



Water Resistant (80 Minutes) 3.30z (98mL)



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Manufactured for bū brands, Ic, Azusa, CA 91702

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octinoxate, octocrylene, octisalate, avobenzone, and homosalate spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70325-5002
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	10 g in 100 mL	
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7.5 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R)			
ETHYLHEXYL METHO XYCRYLENE (UNII: S3KFG6Q5X8)			
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8 D3)			
DIPHENYLSILO XY PHENYL TRIMETHICO NE (UNII: I445L28B12)			
VINYLPYRROLIDO NE/HEXADECENE COPOLYMER (UNII: KFR5QEN0 N9)			
OCTYLDODECANOL (UNII: 461N1O614Y)			
TOCOPHEROL (UNII: R0ZB2556P8)			
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)			
.ALPHABISABOLOL, (+/-)- (UNII: 36 HQN158 VC)			

	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:70325-5002-3	98 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/0 1/20 16	
ı	2 NDC:70325-5002-1	30 mL in 1 BOTTLE; 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		832280635	MANUFACTURE(70325-5002)	

Revised: 1/2021 Bu Brands, LLC