BIG CLOUD DEFEND HYBRID FORMULA WITH ZINC- spf 30 sunscreen spray, suspension
Bell International Laboratories, 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.

Dollar Shave Club Big Clound Defend SPF 30 Sprayable Sunscreen Lotion

Active Ingredient

Homosalate 2.9%, Octisalate 4.9%, Octocrylene 7.6%, Zinc Oxide 5.3%

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

Contents under pressure. Do not puncture or incinerate. Do not store at temperatures above 120 oF.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply 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 onto face. Spray onto hands then apply to face

do not apply in windy conditions. Use in a well-ventilated area.

Reapply after 80 minutes of swimming or sweating, immediately after towel drying, and 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 wtih a broad spectrum SPF value of 15 or higher and other sun protection measures including: Limit time in the sun, especially from 10am-2pm. Wear logn-sleeved shirts, pants, hats, and sunglasses.

Children under 6 months of age: Ask a doctor

Other Information

Protect this product from excessive heat and direct sun.

May stain or damage some fabrics or surfaces

Avoid long-term storage above 104 oF

Inactive Ingredients

water, butyloctyl salicylate, methyl dihydroabietate, coconut alkanes, potassium cetyl phosphate, propanediol, microcrystalline cellulose, caprylyl glycol, fragrance, rubus ideaus (raspberry) seed oil, oryza sativa (rice) bran extract, aloe barbadensis leaf juice, butyrospermum parkii (shea) butter, terminalia ferdinandiana fruit extract, rosmarinus officinalis (rosemary) leaf extract, opuntia vulgaris extract, helianthus annuus (sunflower) extract, tocopherol, cetearyl alcohol, glycerin, cetyl palmitate, sorbitan palmitate, triethoxycaprylylsilane, ethyl ferulate, sodium gluconate, bisabolol, cellulose gum, caprylylhydroxamic acid, sorbitan oleate, xanthan gum, coco-caprylate/caprate, sodium benzoate, potassium sorbate, citric acid, phenoxyethanol, Alpha-Isomethyl Ionone, Coumerin, Hydroxyitronellal, Linalool

6 oz can label

BIG CLOUD DEFEND HYBRID FORMULA WITH ZINC

spf 30 sunscreen spray, suspension

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76150-244
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7.6 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.9 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	2.9 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5.3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
LEVOMENOL (UNII: 24WE03BX2T)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
RICE BRAN (UNII: R60QEP13IC)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PRICKLY PEAR FRUIT (UNII: 18V8PAQ629)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
PROPANEDIOL (UNII: 5965N8W85T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ROSEMARY (UNII: IJ67X351P9)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SORBITAN MONOPALMITATE (UNII: 77K6Z421KU)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SHEA BUTTER (UNII: K49155WL9Y)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76150-244-48	170 g in 1 CAN; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/01/2020	

Labeler - Bell International Laboratories, Inc. (967781555)

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