EB EPICURUS SPF 50 THE SUNSCREEN- avobenzone, octocrylene, octinoxate lotion
BIOCROWN BIOTECHNOLOGY CO., LTD

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.

EB Epicurus SPF 50 The Sunscreen

Drug Facts

Active ingredients

Avobenzone 3%

Octocrylene 1.5%

Octinoxate 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

Stop use and ask a doctor
- if rash occurs

Keep out of reach of children
- If this product is swallowed get medical help or contact a Poison Control Centre right away.

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

Sun Protection Measures

- Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with a Broad Spectrun SPF value of 15 of higher and other sun protection measure including:
- limit time in the sun, especially from 10am-2pm
- wear long-sleeve 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

Inactive ingredients

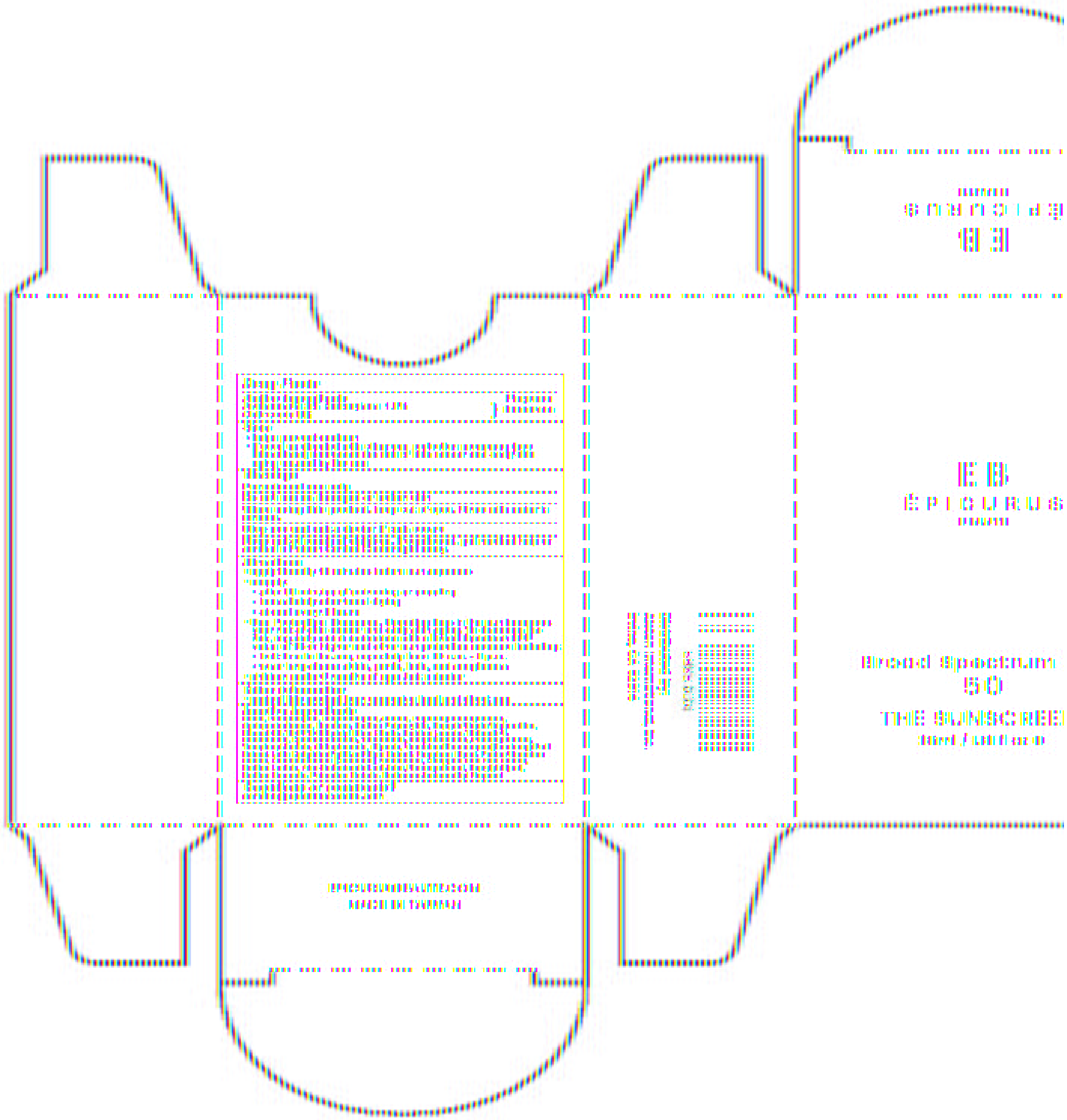
Water, Phospholipids, Butylene Glycol, Alcohol, Polymethylsilsesquioxane, Cyclopentasiloxane, Squalane, Sodium Polyacrylate, Caprylic/Capric Triglycerides, Mineral Oil, Tri-PPG-3 Myristyl Ether Citrate, Sorbitan Laurate, Trideceth-6, Dimethicone, Cyclotetrasiloxane, Triisostearin, Decyl Glucoside, tocopheryl acetate, Chlorphenesin, Glycerin, Vaccinium Macrocarpon (Cranberry) Fruit Extract, Cucumis Sativus (Cucumber) Fruit Extract, Diospyros Kaki Fruit Extract, Sodium Lactate, Aloe Barbadensis Leaf Juice, Phenoxyethanol, Caprylyl Glycol, Sodium Benzoate, Potassium Sorbate, Carbomer, aminomethyl propanol.

Questions?

service@epicurusbeaute.com

Package Labeling:

Card Box
42 x 24 x 81 (mm)



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Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81901-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	30 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	15 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALCOHOL (UNII: 3K9958V90M)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
MINERAL OIL (UNII: T5L8T28FGP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
2,4,6,8-TETRAMETHYLTETRAPHENYLCYCLOTETRASILOXANE, (2.ALPHA.,4.ALPHA.,6.BETA.,8.BETA.)- (UNII: 2F641J843Q)	
PHOSPHATIDYLCHOLINE, SOYBEAN (UNII: 1T6N4D9YV6)	
PPG-3 MYRISTYL ETHER (UNII: 7913J43WZ5)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
WATER (UNII: 059QF0KO0R)	
SQUALANE (UNII: GW89575KF9)	
PPG-1 TRIDECETH-6 (UNII: 1K7417JX6Q)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIISOSTEARIN (UNII: 71503RH8KG)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIOSPYROS KAKI LEAF (UNII: Q71GF9OBNO)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SORBITAN MONOLAURATE (UNII: 6W9PS8B71J)	
CRANBERRY JUICE (UNII: Y74M3X3345)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
CUCUMBER (UNII: YY7C30VXJT)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM ACRYLATE (UNII: 7C98FKB43H)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81901-001-35	35 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/2021	

Labeler - BIOCROWN BIOTECHNOLOGY CO., LTD (656300956)

Establishment

Name	Address	ID/FEI	Business Operations
BIOCROWN BIOTECHNOLOGY CO., LTD		656300956	manufacture(81901-001)

Revised: 6/2021 BIOCROWN BIOTECHNOLOGY CO., LTD