BRICKELL ELEMENT DEFENSE MOISTURIZER SPF-45- octocrylene, octisalate, zinc oxide cream BRICKELL BRANDS LLC

BRICKELL Element Defense Moisturizer SPF-45

Drug Facts

Active Ingredients

Octocrylene 10.00% Octisalate 5.00% Zinc Oxide 5.00%

Purpose

Sunscreen

Uses:

- Helps prevent sunburn.
- higher SPF gives more sunburn protection
- 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:

not intended for ingestion 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 or irritation develops and lasts.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

If pregnant or breast-feeding,

ask a health professional before use.

Directions:

• Apply liberally 15 minutes before sun exposure.

- Children under 6 months of age: ask a doctor.
- Reapply:
- after 40 minutes of swimming or sweating
- immediately after towel drying
- at least every2 hourr
- Spending time in the sun increases your risk of skin cancer and early skin aging. To
 decrease this risk, regularly use sunscreen with broad spectrum protection SPF of 15
 or higher, along with other sun protection measues including: SUN PROTECTION
 MEASURES:
- Limit time in the sun, especially between 10 am 2 pm.
- Wear long-sleeve shirts, pants, hats and sunglasses.

Inactive Ingredients:

Acrylates Copolymer, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Camellia Sinensis (Green Tea) Extract, Caprylic/Capric Triglyceride, Citrullus Lantatus (Watermelon) Extract, Decyl Glucoside, Ethylhexylglycerin, Glycerin, Helianthus Annuus (Sunflower) Oil, C13-14 Isoparaffin, Laureth-7, Phenoxyethanol, polyacrylamide, Tocopheryl Acetate (Vitamin E), Tridecyl Salicylate.

Other Information:

• Protect the product in this container from excessive heat and direct sun.

Package Labeling:

BRICKELL

ELEMENT DEFENSE MOISTURIZER

With Sunflower, Green Tea, & Vitamin E

HYDRATANT **ELEMENT DEFENSE**

Avec du tournesol, du thé vert. et de la vitamine E

NATURAL ZINC BASED SUNSCREEN

BROAD SPECTRUM SPF 45

WATER RESISTANT (80 MINUTES)

8 OZ | 237 ML.E

Our light, non-greasy moisturizer nourishes your skin with essential nutrients while providing broad-spectrum protection from harmful UVA/B rays. Oil-free and won't clog pores.

 $\underline{\text{Directions:}}$ Apply to skin that is exposed to the sun. For all skin types. Can be used on the face or body.

Notre crème hydratante légère et non grasse nourrit votre peau de nutriments essentiels tout en offrant une protection à large spectre contre les rayons UVA/Bnocifs. Sans huile et n'obstrue pas les pores.

Mode d'emploi: Appliquer sur toutes les parties de la peau exposée au soleil. Pour tous les types de peau et peut être utilisé sur le visage ou le corps.

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Made in USA | Fabriqué aux États-Unis For Brickell Men's Products South Portland, ME 04106 483 Green Lanes, London, N13 4BS, UK brickellmensproducts.com | 1-877-598-0060



BRICKELL ELEMENT DEFENSE MOISTURIZER SPF-45

octocrylene, octisalate, zinc oxide cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:82247-234

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Basis of Strength Ingredient Name Strenath

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	50 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
WATER (UNII: 059QF0KO0R)		
GREEN TEA LEAF (UNII: W2ZU1RY8B0)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
WATERMELON (UNII: 231473QB6R)		
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
GLYCERIN (UNII: PDC6A3C0OX)		
SUNFLOWER OIL (UNII: 3W1JG795YI)		
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)		
LAURETH-7 (UNII: Z95S6G8201)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
TRIDECYL SALICYLATE (UNII: AZ Q08K38Z1)		

l	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1	NDC:82247-234- 00	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/21/2021		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M020	09/21/2021		

Labeler - BRICKELL BRANDS LLC (081141606)

Revised: 11/2023 BRICKELL BRANDS LLC