

BALI BODY SPF15 BRONZE SHIMMERING TANNING- avobenzone, octisalate, octocrylene gel
Bali Body Pty Ltd

BALI BODY SPF15 BRONZE SHIMMERING TANNING GEL

Drug Facts

Active ingredients:

Avobenzone 2.0%

Octisalate 5.0%

Octocrylene 7.0%

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 ageing 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 centre right away. Please refer to balibody.com for further sun safety instructions.

Directions

- Apply liberally 15 minutes before sun exposure.

- Re-apply your BB at least every 2 hours
- Wear a water resistant sunscreen if swimming or sweating
- **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin ageing.
- To decrease the risk, regularly use a sunscreen with Broad Spectrum SPF value of 15 or higher and other sun protection measures including
- Limit time in the sun, especially from 10am - 2pm.
- Wear long 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. Report serious adverse events to: AMS Fulfillment 29010 Commerce Drive, Valencia CA 91355

Inactive ingredients

Petrolatum, Caprylic/Capric Triglyceride, Mineral Oil, C12-15 Alkyl Benzoate, Sorbitan Stearate, Propylene Glycol, Mica, Stearalkonium Hectorite, Iron Oxides, Propylene Carbonate, Glycine Soja (Soybean) Oil, Fragrance/Parfum, Bisabolol, Xanthan Gum, Beta-Carotene, Daucus Carota Sativa (Carrot) Root Extract, Tocopherol, BHT, Tocopheryl Acetate, Isochrysis Galbana Extract.

Product Packaging



BALI BODY SPF15 BRONZE SHIMMERING TANNING			
avobenzone, octisalate, octocrylene gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70630-0038

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	70 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ISOCHRYSIS GALBANA WHOLE (UNII: H22FH39EGN)	
BETA CAROTENE (UNII: 01YAE03M7J)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
XANTHAN GUM (UNII: TTV12P4NEE)	
STEARALKONIUM HECTORITE (UNII: OLX698AH5P)	
SOYBEAN OIL (UNII: 241ATL177A)	
MICA (UNII: V8A1AW0880)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
LEVOMENOL (UNII: 24WE03BX2T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARROT (UNII: L56Z1JK48B)	
PETROLATUM (UNII: 4T6H12BN9U)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
MINERAL OIL (UNII: T5L8T28FGP)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70630-0038-1	150 g in 1 JAR; Type 0: Not a Combination Product	05/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/01/2025	

Labeler - Bali Body Pty Ltd (757840223)