

**BALI BODY BB CREAM SPF 15 NATURAL- octocrylene, octinoxate, avobenzone, oxybenzone cream**

**Bali Body Pty 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.*

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**Bali Body BB Cream SPF 15 Natural**

**Product Information / Drug Facts**

**Directions:**

Apply to clean skin with fingertrips. Layer for additional coverage.

**Warnings:**

For external use only. Keep out of direct sunlight or other sources of strong light. Product to be stored between 5-28°C. Discontinue use if irritation occurs. Subtle variations in appearance and texture of this product in no way affect its integrity.

**Keep out of reach of children.**

Please refer to [balibodyco.com](http://balibodyco.com) for further sun-safety instructions.

**Use:**

Helps prevent sunburn, If used with other sun protection measures decreases the risk of skin cancer.

**Active ingredients:**

Octocrylene 6.0%

Octinoxate 5.0%

Avobenzone 3.0%

Oxybenzone 3.0%

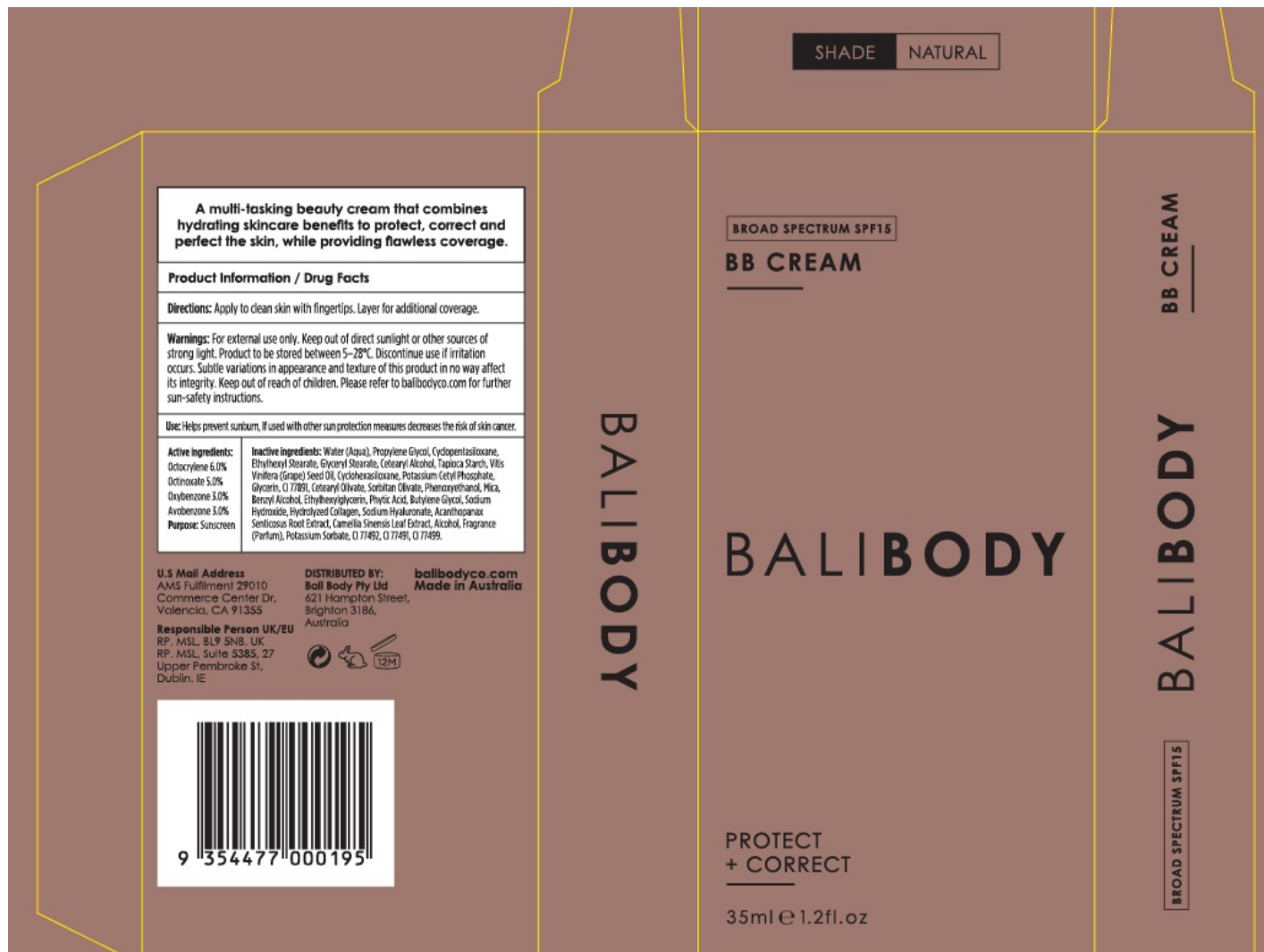
**Purpose:**

Sunscreen

**Inactive ingredients:**

Water (Aqua), Propylene Glycol, Cyclopentasiloxane, Ethylhexyl Stearate, Glyceryl Stearate, Cetearyl Alcohol, Tapioca Starch, Vitis Vinifera (Grape) Seed Oil, Cyclohexasiloxane, Potassium Cetyl Phosphate, Glycerin, CI 77891, Cetearyl Oliviate, Sorbitan Oliviate, Phenoxyethanol, Mica, Benzyl Alcohol, Ethylhexylglycerin, Phytic Acid, Butylene Glycol, Sodium Hydroxide, Hydrolyzed Collagen, Sodium Hyaluronate, Acanthopanax Senticosus Root Extract, Camellia Sinensis Leaf Extract, Alcohol, Fragrance (Parfum), Potassium Sorbate, CI 77492, CI 77491, CI 77499.

## Package Labeling:



## BALI BODY BB CREAM SPF 15 NATURAL

octocrylene, octinoxate, avobenzone, oxybenzone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70630-0029
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	60 mg in 1 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	50 mg in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	30 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>FYTIC ACID</b> (UNII: 7IGF0S7R8I)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ETHYLHEXYL STEARATE</b> (UNII: EG3PA2K3K5)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>GRAPE SEED OIL</b> (UNII: 930MLC8XGG)	
<b>STARCH, TAPIOCA</b> (UNII: 24SC3U704I)	
<b>CYCLOMETHICONE 6</b> (UNII: XHK3U310BA)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>POTASSIUM CETYL PHOSPHATE</b> (UNII: 03KCY6P7UT)	
<b>CETEARYL OLIVATE</b> (UNII: 58B69Q84JO)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>ELEUTHERO</b> (UNII: ZQH6VH092Z)	
<b>SORBITAN OLIVATE</b> (UNII: MDL271E3GR)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70630-0029-1	1 in 1 BOX	03/25/2022	
1		35 mL in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/25/2022	

**Labeler** - Bali Body Pty Ltd (757840223)

Revised: 3/2022

Bali Body Pty Ltd