

BALI BODY BB CREAM SPF 15 TAN- 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.

Bali Body BB Cream SPF 15 Tan

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 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%

Oxybenzone 3.0%

Avobenzone 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, CI 77492, Cetearyl Oliviate, Sorbitan Oliviate, Phenoxyethanol, Mica, Benzyl Alcohol, Ethylhexylglycerin, Phytic Acid, Sodium Hydroxide, Butylene Glycol, Hydrolyzed Collagen, Sodium Hyaluronate, Acanthopanax Senticosus Root Extract, Camellia Sinensis Leaf Extract, Alcohol, Fragrance (Parfum), Potassium Sorbate, CI 77491, CI 77499.

Package Labeling:

SHADE TAN

BROAD SPECTRUM SPF15

BB CREAM

BALIBODY

BALIBODY

BROAD SPECTRUM SPF15

PROTECT + CORRECT

35ml e 1.2fl.oz

A multi-tasking beauty cream that combines hydrating skincare benefits to protect, correct and perfect the skin, while providing flawless coverage.

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 Australia

balibodyco.com
Made in Australia

9 354477 000201

BALI BODY BB CREAM SPF 15 TAN

octocrylene, octinoxate, avobenzone, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70630-0030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70630-0030-1	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