

**BALI BODY CACAO TANNING OIL SPF15- octocrylene, octinoxate, avobenzone oil**

**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 Cacao Tanning Oil SPF15**

**Product Information / Drug Facts**

**Directions:**

Shake well before use. Apply liberally 20 minutes before sun exposure. Re-apply your BB every 1-2 hours, after swimming or exercise..

**Warnings / Cautions / Sun safety:**

**When using this product**

keep out of eyes. If contact occurs rinse with water to remove.

**Stop use and seek medical advise**

if rash occurs. Wear sun-smart options such as hat and sunglasses.

**Do not use**

on damaged or broken skin. Can aid in the prevention of premature skin ageing.

**Keep out of reach of children.**

**Use:**

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

**Active ingredients:**

Octocrylene 3.0%,

Octinoxate 2.0%,

Avobenzone 1.5%.

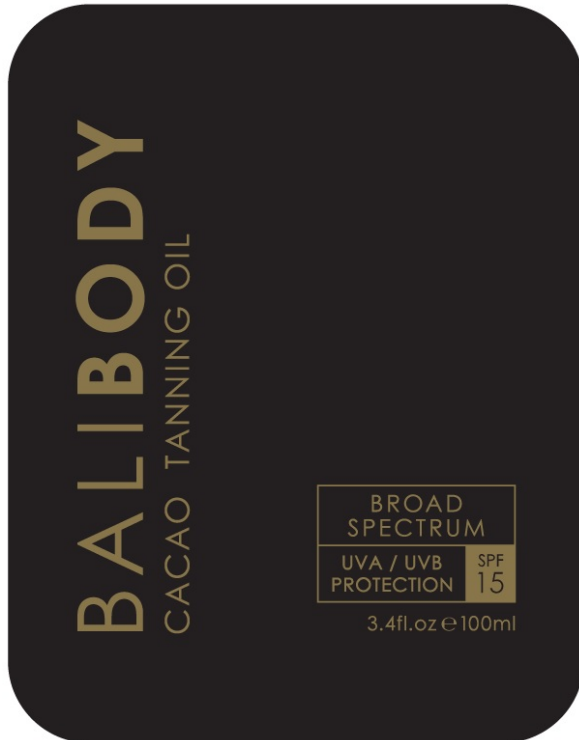
**Purpose:**

# Sunsreen

## Inactive ingredients:

Vitis Vinifera (Grape) Seed Oil, Cocos Nucifera (Coconut) Oil, Olea Europaea (Olive) Fruit Oil, Theobroma Cacao (Cocoa) Seed Powder, Dicaprylyl Carbonate, Octocrylene, Ethylhexyl Methoxycinnamate, Hydrogenated Soy Polyglyceride, Butyl Methoxydibenzoylmethane, Glycine Soja (Soybean) Oil, Tocopherol, BHT, C15-23 Alkane.

## Package Labeling:



## BALI BODY CACAO TANNING OIL SPF15

octocrylene, octinoxate, avobenzone oil

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70630-0022
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	30 mg in 1 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	20 mg in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	15 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>GRAPE SEED OIL</b> (UNII: 930MLC8XGG)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>COCOA</b> (UNII: D9108TZ9KG)	
<b>DICAPRYLYL CARBONATE</b> (UNII: 609A3V1SUA)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>C15-23 ALKANE</b> (UNII: J3N6X3YK96)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70630-0022-1	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/20/2022	

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

Revised: 2/2022

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