

**BALI BODY CACAO TANNING OIL SPF6- 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 SPF6**

**Product Information / Drug Facts**

**Directions:**

Shake well before use. Apply liberally 15 minutes before sun exposure. Children under 6 months old: Ask a doctor. Re-apply every 2 hours. Use water-resistant sunscreen if swimming or sweating. Store in a cool dry place.

**Warnings / Cautions / Sun safety:**

Spending time in the sun increases your risk of skin cancer and early skin ageing. This product has been shown only to prevent sunburn, not skin cancer or early skin ageing.

**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. Always wear a hat, protective clothing and sunglasses.

**Keep out of reach of children.**

**Use:**

Helps prevent sunburn,

**Active ingredients:**

Octocrylene 1.0%,

Octinoxate 1.0%,

Avobenzone 0.5%.

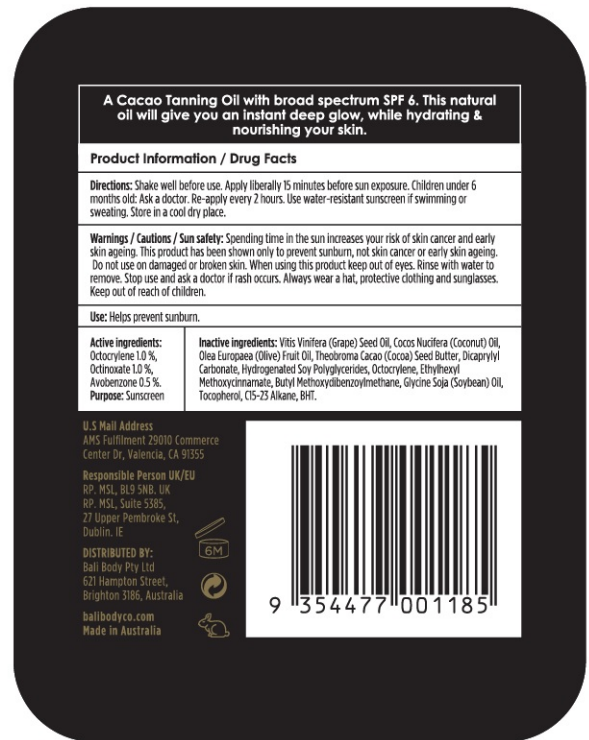
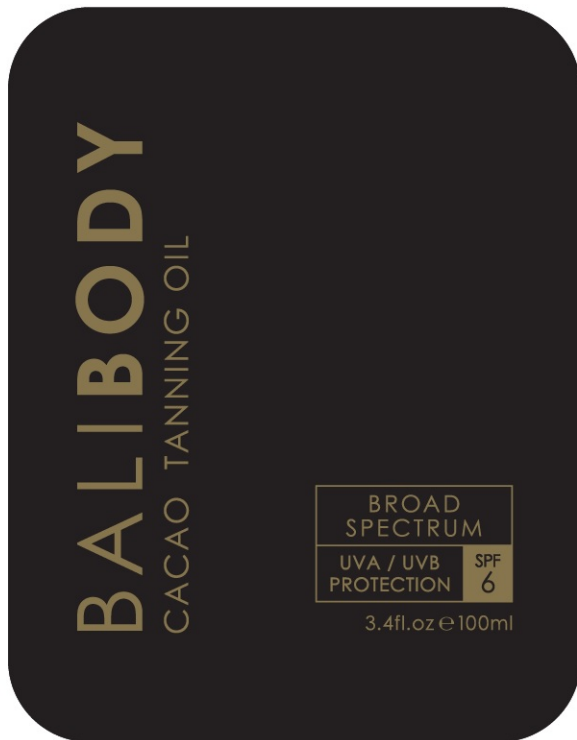
## Purpose:

Sunsreen

## Inactive ingredients:

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

## Package Labeling:



## BALI BODY CACAO TANNING OIL SPF6

octocrylene, octinoxate, avobenzone oil

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70630-0023
<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	10 mg in 1 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	10 mg in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	5 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: 609A3VISUA)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>C15-23 ALKANE</b> (UNII: J3N6X3YK96)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70630-0023-1	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

Bali Body Pty Ltd