

**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.

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%,
Octinoxate 1.9%,
Avobenzone 1.5%.

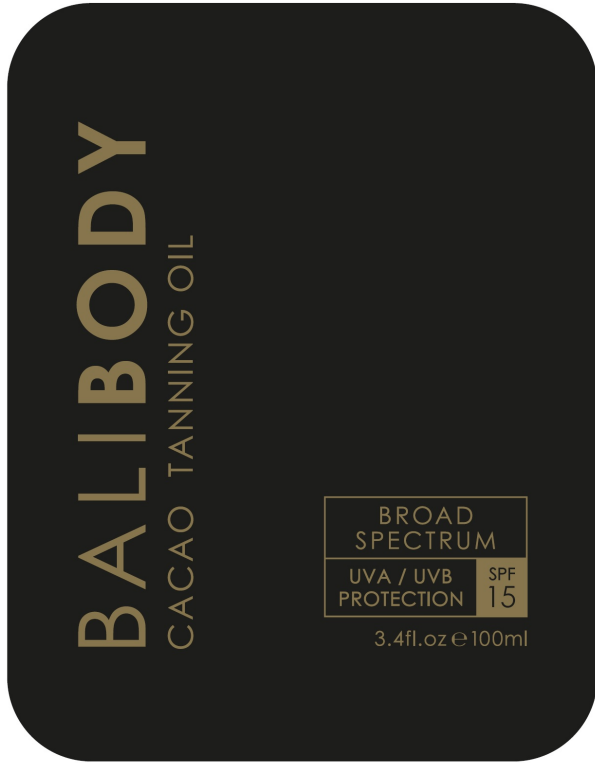
Purpose:

Sunsreen

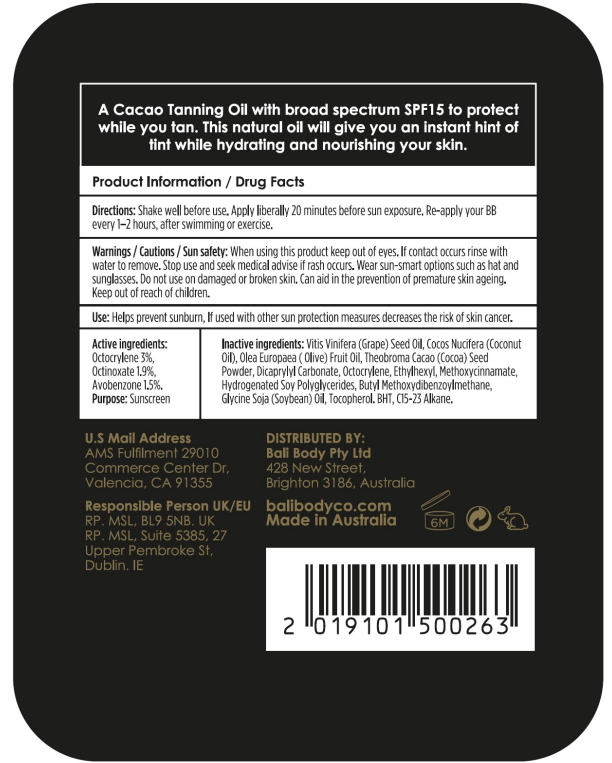
Inactive ingredients:

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:



FRONT



BACK

CACAO TANNING OIL SPF15			
octocrylene, octinoxate, avobenzone oil			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70630-0004
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)		OCTOCRYLENE	30 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	19 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)		AVOBENZONE	15 mg in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70630-0004-1	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2021	

Labeler - Bali Body Pty Ltd (757840223)

Revised: 11/2021

Bali Body Pty Ltd