

**BALI BODY CACAO TANNING OIL SPF 15- octocrylene, octisalate,
avobenzene 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.

Bali Body Cacao Tanning Oil SPF 15

Drug Facts

Active ingredients

Octocrylene 9%

Octisalate 5%

Avobenzene 3%

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (**see directions**) decreases the risk of skin cancer and early skin ageing caused by the sun

Warnings

For external use only.

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.

Keep out of reach of children.

If product is swallowed, get medical help or contact a poison control centre right away.

Please refer to balibody.com for further sun safety instructions.

Directions

Shake well before use. Apply liberally 15 minutes before sun exposure. Re-apply your BB every 1-2 hours. Wear a water resistant sunscreen if swimming or sweating. Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

- Limit time in the sun, especially from 10 a.m. - 2 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses

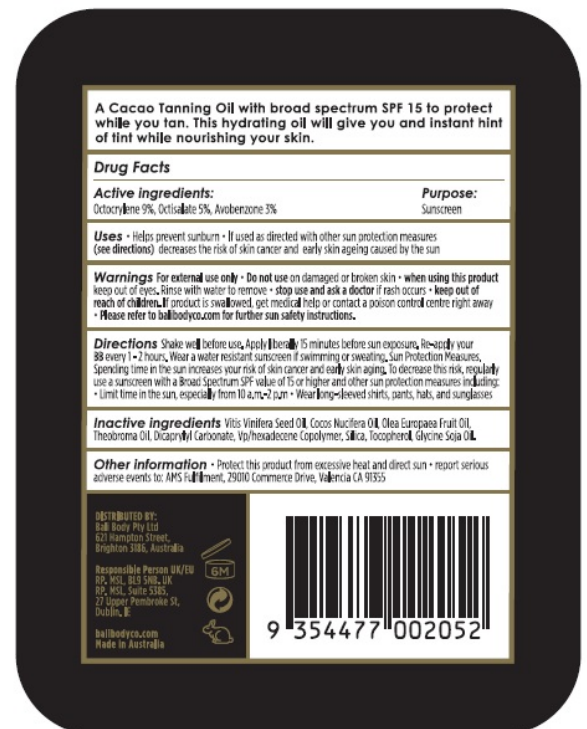
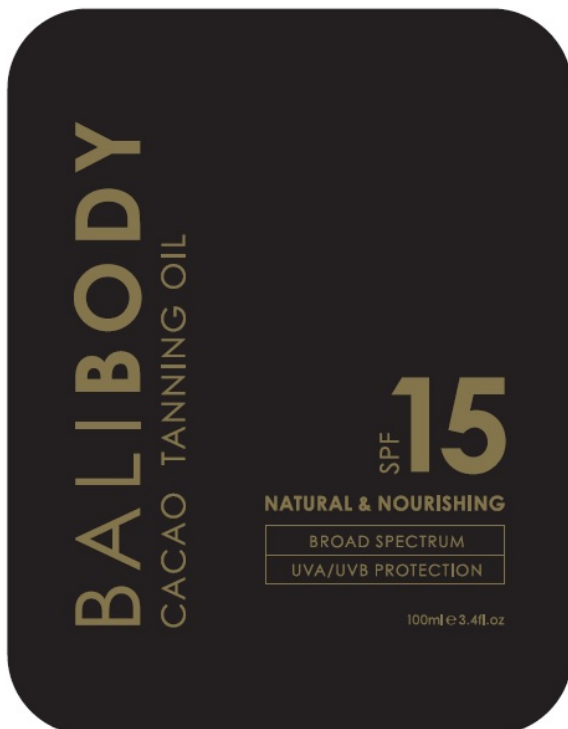
Inactive ingredients

Vitis Vinifera Seed Oil, Cocos Nucifera Oil, Olea Europaea Fruit Oil, Theobroma Oil, Dicaprylyl Carbonate, Vp/hexadecene Copolymer, Silica, Tocopherol, Glycine Soja Oil.

Other information

- Protect this product from excessive heat and direct sun
- Report serious adverse events to: AMS Fulfilment, 29010 Commerce Drive, Valencia CA 91355

Package Labeling



octocrylene, octisalate, avobenzone oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70630-0034
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	90 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
COCOA BUTTER (UNII: 512OYT1CRR)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
COCONUT OIL (UNII: Q9L0O73W7L)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70630-0034-1	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	12/01/2023	

Labeler - Bali Body Pty Ltd (757840223)

Revised: 8/2023

Bali Body Pty Ltd