

**BALI BODY WATERMELON TANNING OIL SPF 6- 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.*

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**Bali Body Watermelon Tanning Oil SPF6**

**Drug Facts**

**Active ingredients**

Octisalate 5%

Octocrylene 3%

Avobenzene 1%

**Purpose**

Sunscreen

**Uses**

- Helps prevent sunburn

**Warnings**

**Skin Cancer/Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

**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.

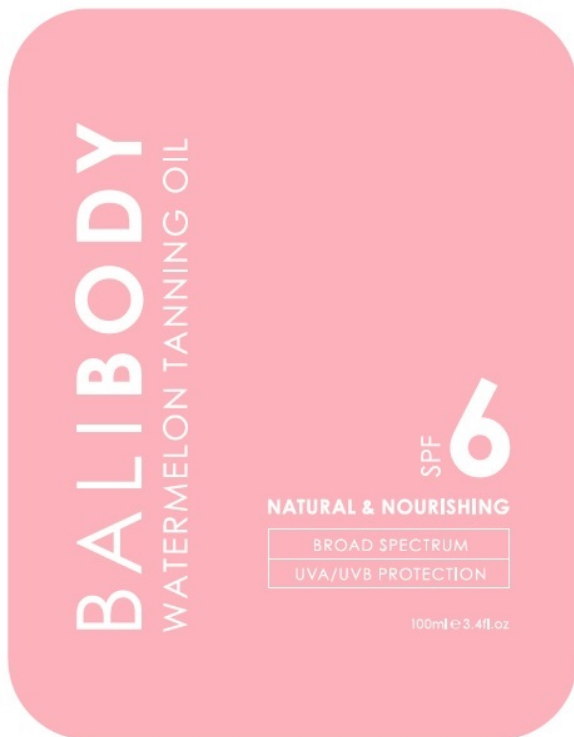
## Inactive ingredients:

Vitis Vinifera Seed Oil, Cocos Nucifera Oil, Prunus Amygdalus Dulcis Oil, Dicaprylyl Carbonate, Vp/hexadecene Copolymer, Citrullus Lanatus Seed Oil, Tocopherol, Parfum, Glycine Soja Oil, Benzyl Alcohol, Citronellol, Rose Ketone-4, Geraniol, Linalool, Benzyl Benzoate, Benzyl Salicylate, Cinnamyl Alcohol.

## 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



## BALI BODY WATERMELON TANNING OIL SPF 6

octocrylene, octisalate, avobenzone oil

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70630-0033
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	30 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	10 mg in 1 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>CINNAMYL ALCOHOL</b> (UNII: SS8YOP444F)	
<b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E)	
<b>BENZYL BENZOATE</b> (UNII: N863NB338G)	
<b>GRAPE SEED OIL</b> (UNII: 930MLC8XGG)	
<b>ALMOND OIL</b> (UNII: 66YXD4DKO9)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>DICAPRYLYL CARBONATE</b> (UNII: 609A3V1SUA)	
<b>WATERMELON SEED OIL</b> (UNII: L33J06UQTT)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>VINYLPYRROLIDONE/HEXADECENE COPOLYMER</b> (UNII: KFR5QEN0N9)	
<b>BENZYL SALICYLATE</b> (UNII: WAO5MKN9TU)	
<b>.BETA.-CITRONELLOL, (+/-)-</b> (UNII: 565OK72VNF)	
<b>GERANIOL</b> (UNII: L837108USY)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:70630-0033-1	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2023	

## Marketing Information

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

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