

BALI BODY SPF 15 PINEAPPLE TANNING OIL- octinoxate, octocrylene cream 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 Pineapple Tanning Oil SPF 15

Octinoxate 2.8%

Octocrylene 2.8%

Keep out of reach of children.

A tanning and body oil.

Provides SPF 15 protection.

Shake well before use. Apply liberally 15 minutes before sun exposure.

Children under 6 months: Ask a doctor.

Reapply every 2 hours.

Use water-resistant sunscreen if swimming or sweating.

Store in a cool dry place.

- Grape seed oil;
- Coconut oil;
- Soybean oil;
- Sweet almond oil;
- Pineapple; and
- Vitamin E.

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 help prevent sunburn, not skin cancer or early skin aging.

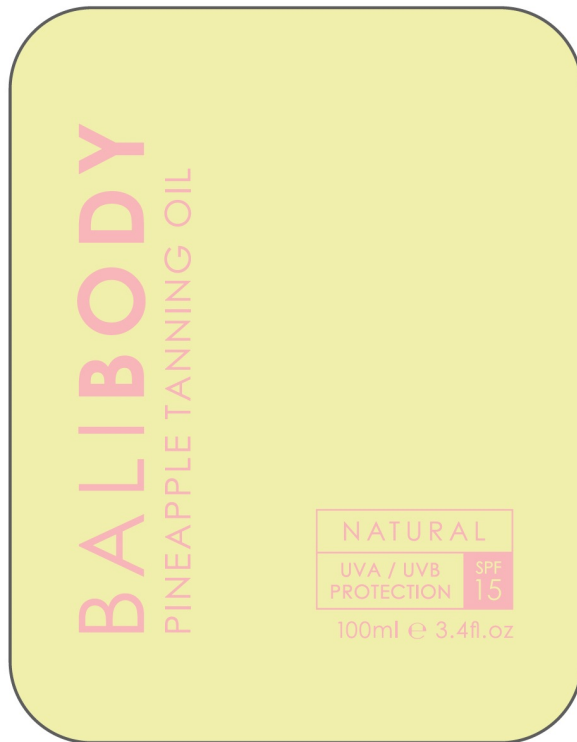
Do not use on damaged or broken skin.

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.

Apply liberally 15 minutes before sun exposure.



BALI BODY SPF 15 PINEAPPLE TANNING OIL			
octinoxate, octocrylene cream oil			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70630-1804
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)		OCTOCRYLENE	2.8 mg in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	2.8 mg in 100 mL
Inactive Ingredients			
Ingredient Name			Strength
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)			
SOYBEAN OIL (UNII: 241ATL177A)			
PINEAPPLE (UNII: 2A88ZO081O)			
COCONUT OIL (UNII: Q9L0O73W7L)			
ALMOND OIL (UNII: 66YXD4DKO9)			
GRAPE SEED OIL (UNII: 930MLC8XGG)			
Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70630-1804-1	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/13/2018	

Labeler - Bali Body Pty Ltd (757840223)

Registrant - Bali Body Pty Ltd (757840223)

Revised: 2/2019

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