

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

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**Bali Body Pineapple Tanning Oil SPF 6**

Octinoxate 2.5%

Octocrylene 2.5%

Keep out of reach of children.

A tanning and body oil.

Provides SPF 6 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.

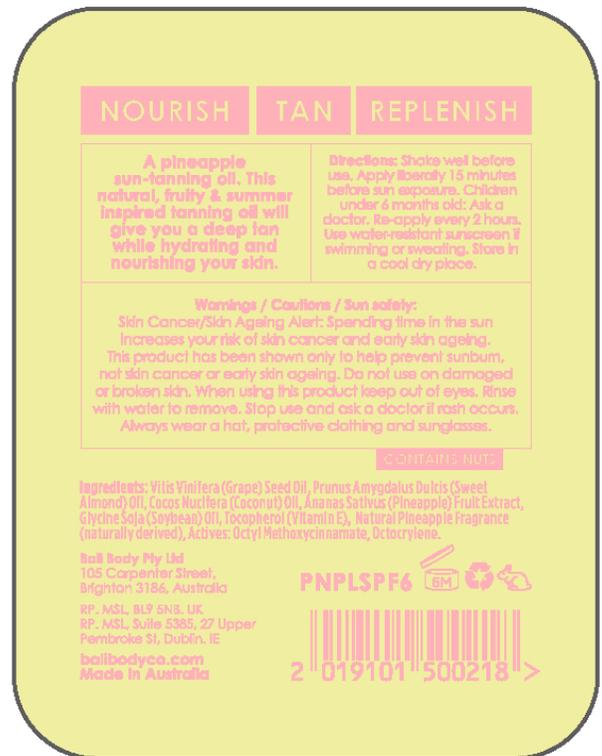
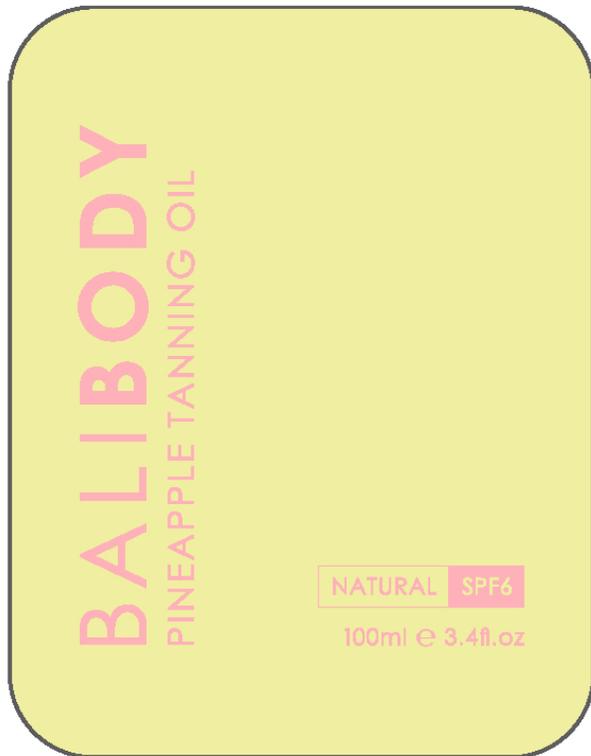
Do not use on damaged or broken skin.

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 PINEAPPLE TANNING OIL SPF 6

octinoxate, octocrylene cream oil

### Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:70630-1801 |
| <b>Route of Administration</b> | TOPICAL        |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength         |
|---|-------------------|------------------|
| <b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE       | 2.5 mg in 100 mL |
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)   | OCTINOXATE        | 2.5 mg in 100 mL |

### Inactive Ingredients

| Ingredient Name                              | Strength |
|--|----------|
| <b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1) |          |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)        |          |
| <b>PINEAPPLE</b> (UNII: 2A88ZO081O)          |          |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)        |          |
| <b>ALMOND OIL</b> (UNII: 66YXD4DKO9)         |          |
| <b>GRAPE SEED OIL</b> (UNII: 930MLC8XGG)     |          |

## Packaging

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70630-1801-1 | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/21/2018           |                    |

## Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352                                  | 05/21/2018           |                    |

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

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

Revised: 10/2019

Bali Body Pty Ltd