

**NATURAL TANNING AND BODY OIL SPF6- 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.

Natural Tanning & Body Oil SPF6

Product Information / Drug Facts

Directions:

Shake well before use. Apply liberally 15 minutes before sun exposure. Children under 6 months old: Ask a doctor. Re-apply every 2 hours. Use water-resistant sunscreen if swimming or sweating. Store in a cool dry place.

Warnings / Cautions / Sun safety:

Spending time in the sun increases your risk of skin cancer or early skin ageing. This product has been shown only to prevent sunburn, not skin cancer or early skin ageing.

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.

Keep out of reach of children.

Use:

Helps prevent sunburn.

Active ingredients:

Octocrylene 3.0%,

Octinoxate 3.0%,

Avobenzone 1.25%.

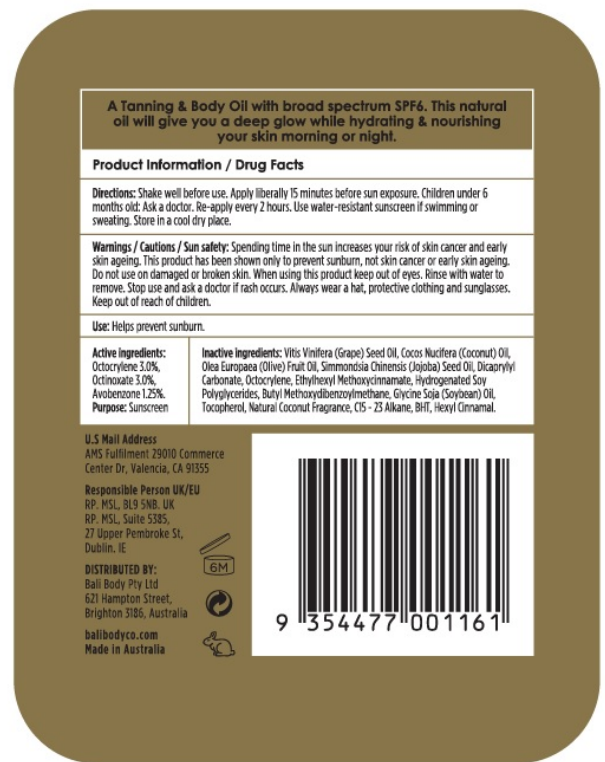
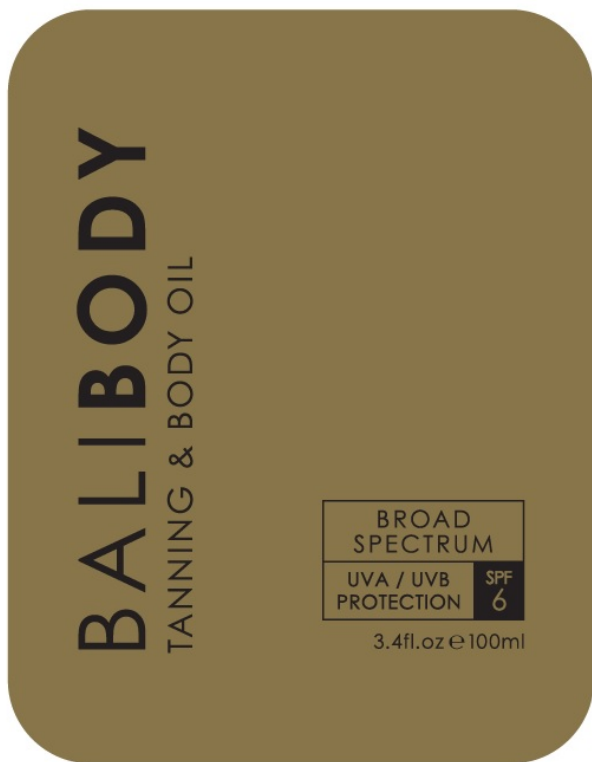
Purpose:

Sunsreen

Inactive ingredients:

Vitis Vinifera (Grape) Seed Oil, Cocos Nucifera (Coconut) Oil, Olea Europaea (Olive) Fruit Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Dicaprylyl Carbonate, Octocrylene, Ethylhexyl Methoxycinnamate, Hydrogenated Soy Polyglycerides, Butyl Methoxydibenzoylmethane, Glycine Soja (Soybean) Oil, Tocopherol, Natural Coconut Fragrance, C15-23 Alkane, BHT, Hexyl Cinnamal.

Package Labeling:



NATURAL TANNING AND BODY OIL SPF6

octocrylene, octinoxate, avobenzene oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70630-0027
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	30 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	30 mg in 1 mL

AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	12.5 mg in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
GRAPE SEED OIL (UNII: 930MLC8XGG)	
COCONUT OIL (UNII: Q9L0O73W7L)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
JOJOBA OIL (UNII: 724GKU717M)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
C15-23 ALKANE (UNII: J3N6X3YK96)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70630-0027-1	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/28/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/28/2022	

Labeler - Bali Body Pty Ltd (757840223)

Revised: 2/2022

Bali Body Pty Ltd