WATERMELON TANNING 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.

Watermelon Tanning 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 and 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:

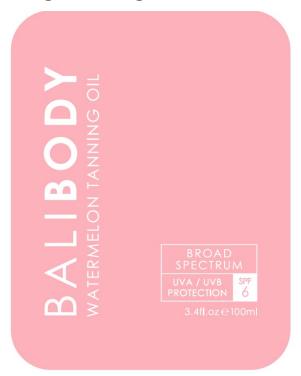
Octocrylene 2.5%, Octinoxate 2.5%, Avobenzone 1%.

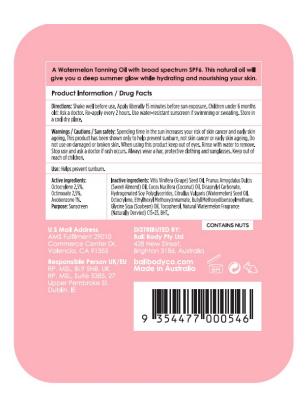
Purpose:

Inactive ingredients:

Vitis Vinifera (Grape) Seed Oil, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Cocos Nucifera (Coconut) Oil, Dicaprylyl Carbonate, Hydrogenated Soy Polyglycerides, Citrullus Vulgaris (Watermelon) Seed Oil, Octocrylene, Ethylhexyl Methoxycinnamate, Butyl Methoxydibenzoylmethane, Glycine Soja (Soybean) Oil, Tocopherol, Natural Watermelon Fragrance (Naturally Dervied), C15-23, BHT.

Package Labeling:





WATERMELON TANNING OIL SPF6

octocrylene, octinoxate, avobenzone oil

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70630-0005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	25 mg in 1 mL		
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	25 mg in 1 mL		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	10 mg in 1 mL		

Inactive Ingredients		
Ingredient Name	Strength	
GRAPE SEED OIL (UNII: 930MLC8XGG)		
ALMOND OIL (UNII: 66YXD4DKO9)		
COCONUT OIL (UNII: Q9L0O73W7L)		
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)		
WATERMELON (UNII: 231473QB6R)		
SOYBEAN OIL (UNII: 241ATL177A)		
TOCOPHEROL (UNII: R0ZB2556P8)		
C15-23 ALKANE (UNII: J3N6X3YK96)		
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:70630- 0005-1	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021		

Marketing In	rketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	01/01/2021		

Labeler - Bali Body Pty Ltd (757840223)

Revised: 10/2021 Bali Body Pty Ltd