

## MOISTURIZING SUNSCREEN SPF 15- zinc oxide and titanium oxide cream cream 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.*

### Moisturising Sunscreen SPF15



Zinc Oxide

Titanium Dioxide

Keep out of reach of children.

A tanning and body oil.

Provides SPF15 protection.

Shake well before use. Apply liberaly 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 cool dry place.

Aqua (purified water), Prunus Amygdalus Dulcis (Sweet Almond) oil, Coco-Caprylate/Capratae, Polyglycerl-3 Polyrincnoleate, Aloe Barbadensis (Aloe Vera) leaf extract, Glycerin (Plant derived), Citrus Paradisi Peel (grapefruit) oil, Butyrospermum Parkii (Shea Butter), Cocos Nucifera Oil (Coconut), Rosa Canina (Rose Hip) fruit oil, Simmondsia Chinensis (Jojoba) oil, Tocopherol (Vitamin E), Gylceryl Caprylate, Isostearic Acid, Natural Coconut Fragrance\*, Phenoxyethanol, Hexyl Cinnamal.

\*naturally derived.

Skin Cancer/Skin Ageing 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.

## MOISTURIZING SUNSCREEN SPF 15

zinc oxide and titanium oxide cream cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70630-1604
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4 mg in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	24.6 mg in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)	
JOJOBA OIL (UNII: 724GKU717M)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
WATER (UNII: 059QF0KO0R)	
ALMOND OIL (UNII: 66YXD4DKO9)	
GRAPEFRUIT OIL (UNII: YR377U58W9)	
SHEA BUTTER (UNII: K49155WL9Y)	
ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70630-1604-1	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/20/2016	

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

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

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Bali Body Pty Ltd