

**BALI BODY FACE AND BODY SUNSCREEN SPF 50- avobenzone, homosalate, octisalate, octocrylene aerosol**

**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 Face and Body Sunscreen Spray SPF50**

**Drug Facts**

**Active ingredients**

Avobenzone - 1.8%

Homosalate - 9%

Octisalate - 3%

Octocrylene - 6%

**Purpose**

Sunscreen

**Uses**

- Helps prevent sunburn
- If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin ageing caused by the sun.

**Warnings**

**For external use only**

**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

**Keep out of reach of children.**

If product is swallowed, get medical help or contact a Poison Control Center right away.

### **Contents under pressure.**

Do not puncture or incinerate. Do not store at a temperature above 120°F. Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

### **Directions**

- Shake well before use. Hold bottle 4-5 inches away from your body & spray a generous amount to exposed dry skin.
- Apply liberally 15 minutes before sun exposure
- Reapply:
  - After 80 minutes of swimming or sweating
  - Immediately after towel drying
  - At least every 80 minutes
- **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin ageing. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
  - Limit time in the sun, especially from 10 a.m. - 2 p.m.
  - Wear long-sleeve shirts, pants, hats, and sunglasses
  - Children under 6 months: Ask a doctor

### **Inactive ingredients**

Dimethyl Ether, Water, Beeswax, C12-15 Alkyl Benzoate, Cetyl Dimethicone, Cocoglycerides, Glycerin, PEG-15 Cocamine, PEG-40 Stearate, Phenoxyethanol, Saccharide Isomerate, Caprylyl Glycol, Disodium EDTA, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Caprylhydroxamic Acid, Tocopheryl Acetate, Aloe Barbadensis Extract, Citric Acid, Sodium Citrate.

### **Other information**

- Protect this product from excessive heat and direct sun
- Report serious adverse events to: AMS Fulfilment 29010 Commerce Centre Drive, Valencia CA, 19355

### **Company Information**

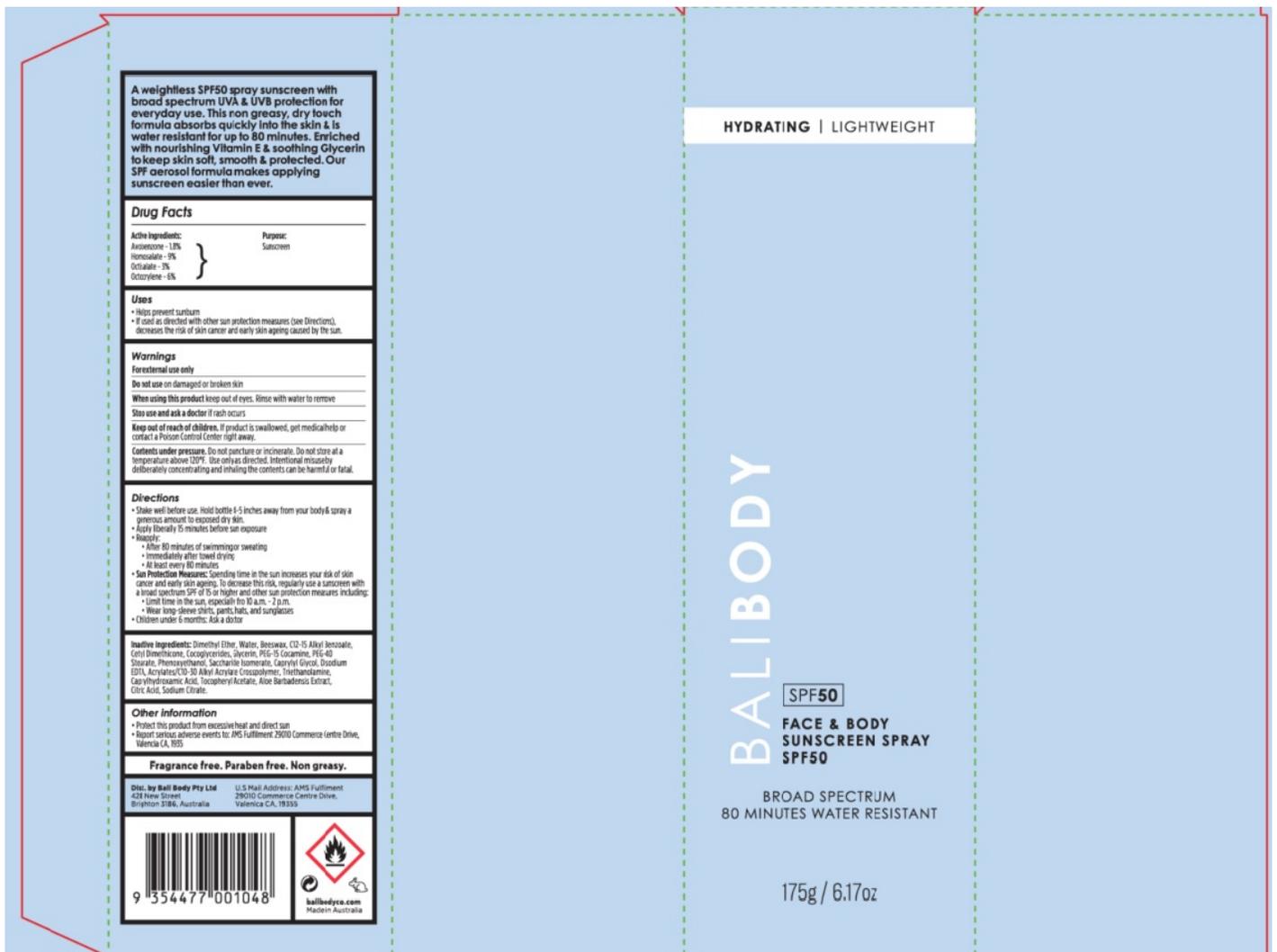
Dist. by Bali Body Pty Ltd

428 New Street

Brighton 3186, Australia

balibodyco.com

### **Product Packaging**



## BALI BODY FACE AND BODY SUNSCREEN SPF 50

avobenzone, homosalate, octisalate, octocrylene aerosol

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70630-0024
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	30 mg in 1 g
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	60 mg in 1 g
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	90 mg in 1 g
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	18 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>DIMETHYL ETHER</b> (UNII: AM13FS69BX)	

<b>WATER</b> (UNII: 059QF0KO0R)
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)
<b>CETYL DIMETHICONE 45</b> (UNII: IK315POC44)
<b>ALOE VERA WHOLE</b> (UNII: KIZ4X2EHYX)
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)
<b>PEG-15 COCAMINE</b> (UNII: 8L6LB12TSJ)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>CARBOMER INTERPOLYMER TYPE A (55000 CPS)</b> (UNII: 59TL3WG5CO)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>COCO-GLYCERIDES</b> (UNII: ISE9I7DNUG)
<b>PEG-40 STEARATE</b> (UNII: ECU18C66Q7)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>SACCHARIDE ISOMERATE</b> (UNII: W8K377W98I)
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)
<b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70630-0024-1	1 in 1 BOX	02/22/2022	
1		175 g in 1 CAN; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/22/2022	

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

Revised: 2/2022

Bali Body Pty Ltd