

BALI BODY HYDRATING BODY SUNSCREEN SPF50- avobenzone, homosalate, octisalate, octocrylene lotion

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.

Bali Body Hydrating Body Sunscreen SPF50

Drug Facts

Active ingredients

Avobenzone - 3.00% w/w

Homosalate - 15.00% w/w

Octisalate - 5.00% w/w

Octocrylene - 10.00% w/w

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.

Directions

- 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

Water, Beeswax, Cocoglycerides, Cetyl Dimethicone, Silica, PEG-15 Cocamine, Glycerin, C12-15 Alkyl Benzoate, PEG-40 Stearate, Tocopheryl Acetate, Phenoxyethanol, Caprylyl Glycol, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Triethanolamine, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Disodium EDTA, Caprylhydroxamic Acid, Aloe Barbadensis Extract.

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

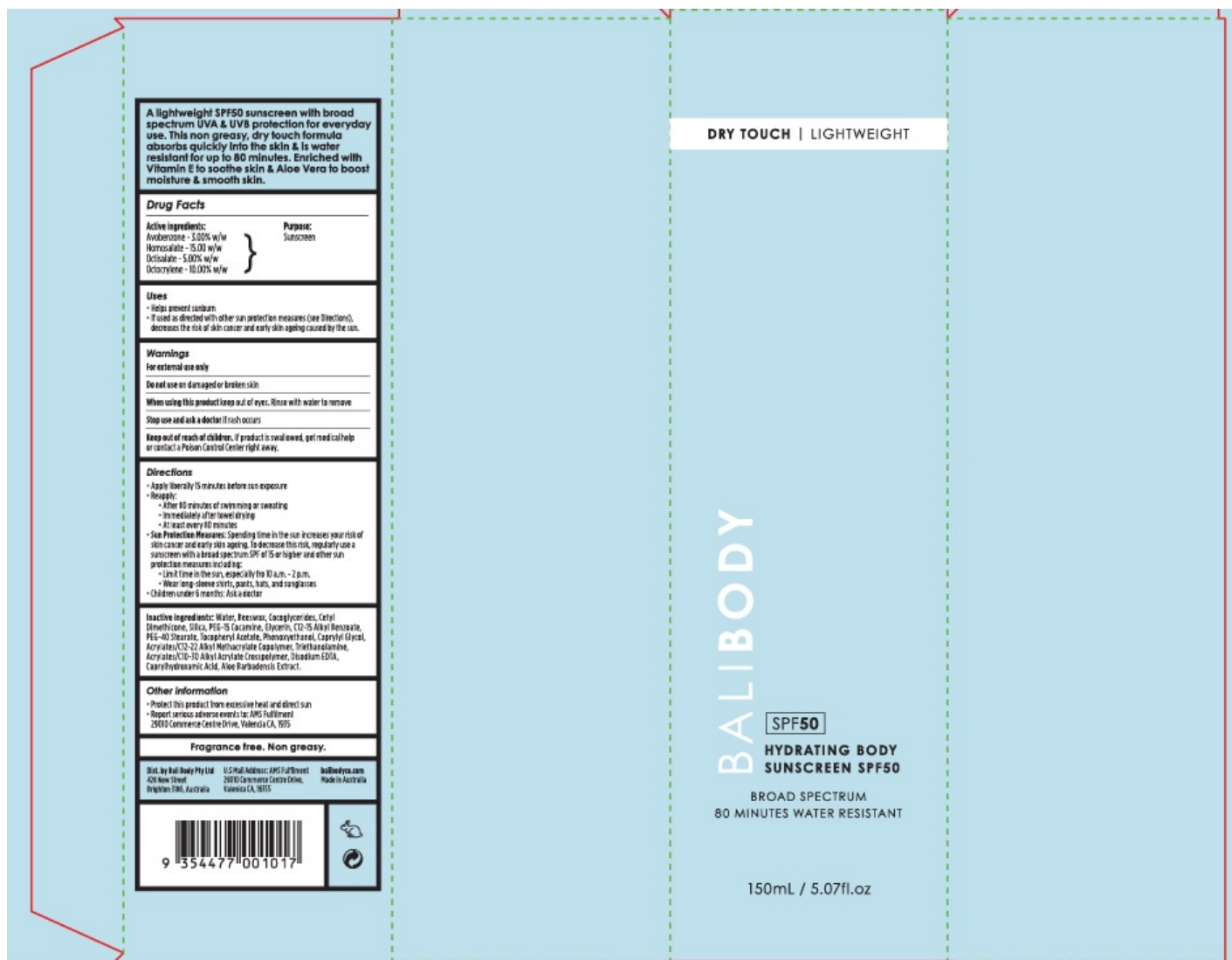
Dist. by Bali Body Pty Ltd

428 New Street

Brighton 3186, Australia

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Product Packaging



BALI BODY HYDRATING BODY SUNSCREEN SPF50

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70630-0025
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	150 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
WATER (UNII: 059QF0KO0R)
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)
CETYL DIMETHICONE 45 (UNII: IK315POC44)
ALOE VERA WHOLE (UNII: KIZ4X2EHYX)
YELLOW WAX (UNII: 2ZA36H0S2V)
PEG-15 COCAMINE (UNII: 8L6LB12TSJ)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
GLYCERIN (UNII: PDC6A3C0OX)
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
COCO-GLYCERIDES (UNII: ISE9I7DNUG)
PEG-40 STEARATE (UNII: ECU18C66Q7)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
TROLAMINE (UNII: 9O3K93S3TK)
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70630-0025-1	1 in 1 BOX	02/25/2022	
1		150 mL in 1 BOTTLE, PUMP; 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	02/25/2022	

Labeler - Bali Body Pty Ltd (757840223)

Revised: 2/2022

Bali Body Pty Ltd