BALI BODY HYDRATING FACE 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 Face Sunscreen SPF50

Drug Facts

Active ingredients

Homosalate - 15.00% w/w

- Octocrylene 10.00% w/w
- Octisalate 5.00% w/w
- Avobenzone 3.00% 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:
- At least every 80 minutes
- Use a water resistant sunscreen if swimming or sweating
- **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, Cocoglycerides, Cetyl Dimethicone, Silica, PEG-15 Cocamine, Stearyl Behenate, Glycerin, C12-15 Alkyl Benzoate, PEG-40 Stearate, Polyhydroxystearic Acid, Tocopheryl Acetate, Phenoxyethanol, Caprylyl Glycol, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Disodium EDTA, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Caprylhydroxamic Acid, Triethanolamine, 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

balibodyco.com

Product Packaging

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	A hydraling facial SPF50 sunscreen lolion with broad spectrum UVA & UVB protection for averyday use. This lightweight fluid formula absorbs quickly to leave a nan greasy, matte finish. Enriched with Vitamin E & soothing Glycerin to nourish your skin while keeping it protected.			
1	Drug Facts	1	FLUID LIGHTWEIGHT	
	Active ingredients: Homssalate - 55,00% w/w Octosylate - 50,00% w/w Avobercore - 3,00% w/w			
	Uses • Helps prevent surburn • If used as directed with other san protection measures (see Anenthem), decreases the risk of skin cancer and early skin ageing caused by the sun,			
	Warnings For external use only	1		
	Do not use on damaged or broken skin When using this product keep out of eyes. Rinse with water	1		
	to remove Stop use and ask a doctor if rash occurs	1		
1	Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.	1		
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	Other information • Protect this product from excessive lead and direct sun • Report serious adverse events for AMS Fulfilment 2000 Commerce Centre Drive, Nationals CA, 1955		SPF 50	
	Fragrance free. Vegan. Non greasy.	1		
	Dist. by Bail Body Pty Ltd U.S. Nail Address: AMS Fulfiment 428 New Street 2900 Commerce Centre Drive, Brighton SIBG, Australia Valenca CA, 1955 bailbodyce.cem		HYDRATING FACE SUNSCREEN SPF50	
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	9 354477 000980		50mL / 1.70fl.oz	
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BALI BODY HYDRATING FACE SUNSCREEN SPF50						
avobenzone, homosalate, octisalate, octocrylene lotion						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:	NDC:70630-0026	
Route of Administration	TOPICAL					
Active Ingredient/Active Moiety						
Ingredient Name			Basis of Stre	ngth	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)			AVOBENZ ONE		30 mg in 1 mL	
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MINE (UNII: 903	(93S3TK)			
.HYDROXAMIC	acid (Unii: Upy805K99W)			
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n Code	Package Description		-	larketing End Date
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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