ANTIOXIDANT BODY SUNSCREEN CREME SPF50 BROAD SPECTRUMavobenzone 30mg/g, homosalate 100mg/g, octocrylene 100mg/g, octisalate 50mg/g, oil NAKED SUNDAY PTY LTD

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# NAKED SUNDAYS ANTIOXIDANT BODY SUNSCREEN CRÈME SPF 50 BROAD SPECTRUM

## **ACTIVE INGREDIENTS**

AVOBENZONE 3 %
HOMOSALATE 10%
OCTISALATE 5 %
OCTOCRYLENE 10%

### **PURPOSE**

**SUNSCREEN** 

## **USE**

- Helps prevents 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.

Skin Cancer/Skin Aging 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

keep out of eyes, Rinse with water to remove

## Stop use & ask doctor

If rash occurs

If product is swallowed, get medical help or contact a poison control center right away

## **Directions**

Apply generously 15 minutes before sun exposure. Use a water-resistant sunscreen if swimming or sweating. Reapply immediately after towel drying. Reapply at least every 2 hours. Children under 6 months of age: Ask a doctor.

## **Sun Protection Measures:**

Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad spectrum SPF value of 15 or higher and other sun protection measures inclusing:

- limit time in the sun, especially from 10:00 AM- 02:00 PM
- Wear long- Sleeved shirts , pants, Hats and sunglasses

## **Inactive Ingredients**

Inactive Ingredients:

Dimethicone, Ethylhexylglycerin, Fragrance, Gluconolactone, Glyceryl Monostearate, Kakadu Plum, Phenoxyethanol, Potassium Cetyl Phosphate, Purified Water, Sodium Benzoate, Sodium Polyacrylate, Tocopherol acetate

Protect the product in this container from excessive heat & direct sun

## **Dosage and Administration**

For External use Only, Apply over skin

### Label

ENRICHED WITH

**SPF 50** 

## Drug Facts:

### Active Ingredients: Purpose: Avobenzone 3%... Homosolate 10%... Octisalate 5%... Octocrylene 10%. Sunscreer Sunscreer Sunscreer Sunscreen

Use:

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.

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- early skin ageing caused by the sun.

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  Stop use and ask a doctor: If rash occurs.

  Keep out of reach of children: If product is swallowed, get medical help or cont act a Polson Control Center right away.

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  Use a vater-resistant sunscreen if swimming or sweating.

  Reapply immediately after towel drying.

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Phenoxyethanol, Potassium Cetyl Phosphate, Purified
Water, Sodium Benzoale, Sodium Polyacrylate,
Tocopherol Acetate

### Other Information:

Protect the product in this container from excessive heat and direct sun.



## Drug Facts: **Drug Facts** (continued) Active Ingredients: Purpose: Avobenzone 3% Homosalate 10% Sunscreen Sunscreen Inactive Ingredients: Dimethicone, Ethylhexylglycerin, Octisalate 5% Octocrylene 10% Sunscreen Sunscreen Fragrance, Gluconolactone, Glyceryl Monostearate, Use: ■ Helps prevent sunburn. ■If used as directed with other sun protection measures Kakadu Plum, Phenoxyethanol, Potassium Cetyl Phosphate, Purified Water, Sodium (see directions), decreases the risk of skin cancer and early skin ageing caused by the warnings: For external use only. Skin Cancer/Skin Aging 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. \*Keep out of reach of children: If product is swallowed, get medical help or contact a Poison Control Center right away. \*Flammable. Keep away from flames and sparks. Wait 5/10 minutes after application before approaching a source of heat or flame, or before smokling. \*Directions: \*\*Apply generously 15 minutes Benzoate, Sodium Polyacrylate, Tocopherol Acetate Other Information: Protect the product in this container from excessive heat and direct sun Directions: ■ Apply generously 15 minutes before sun exposure. ■ Use a water-resistant sunscreen if swimming or sweating. ■Reapply immediately after towel drying. ■Reapply at least every 2 hours. ■ Children under 6 months of age: Ask a doctor. **ANTIOXIDANT BODY** Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: \*Limit time in the sun, especially from 10.00AM-2.00PM \*Wear long-sleeved shirts, pants, hats, and sunplasses. sunglasses

## ANTIOXIDANT BODY SUNSCREEN CREME SPF50 BROAD SPECTRUM

avobenzone 30mg/g, homosalate 100mg/g, octocrylene 100mg/g, octisalate 50mg/g, oil

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81104-900	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL		
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL		

## **Inactive Ingredients**

Ingredient Name	Strength
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
WATER (UNII: 059QF0KO0R)	

F	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:81104-900- 01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2022		
2	NDC:81104-900- 02	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2022		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/01/2022	

# Labeler - NAKED SUNDAY PTY LTD (746918845)

Revised: 12/2023 NAKED SUNDAY PTY LTD