

AUSTRALIAN SANDS SPF 50 SUNSCREEN- avobenzone 3%, homosalate 15%, octisalate 5%, octocrylene 10% spray
Derma Care Research Labs, LLC

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.

Australian Sands SPF 50 CS

Active Ingredients

Avobenzone 3%, Homosalate 15%, Octisalate 5%, Octocrylene 10%

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 aging caused by the sun.

Warnings

For external use only. Flammable: do not use while smoking or near heat or flame.

Do not use on damaged or broken skin. **When using this product** keep out of eyes. Rinse eyes with water to remove. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120 degrees F.

Stop use and ask a doctor if rash occurs.

Keep Out of Reach of Children.

If 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 2 hours

Sun protection measures: spending time in the sun increases your risk of skin cancer and early skin aging. To decrease risk, regularly use a sunscreen with broad

spectrum SPF of 15 or higher and other sun protection measure including:

- limit time in the sun, especially from 10 am to 2 pm
- wear long-sleeved shirts, pants, hats, and sunglasses.
- Children under 6 months: ask a doctor.

Hold container 4 to 6 inches from the skin to apply. Do not spray directly into face. Spray on hands then apply to face. Do not apply in windy conditions. Use in a well-ventilated area.

Inactive Ingredients

Alcohol Denat., Acrylates/Octylacrylamide Copolymer, Argania Spinosa Kernel Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Tocopherol, Ascorbic Acid, Glycerin, Caprylic/Capric Triglyceride, Diethylhexyl Syringylidenemalonate, Fragrance.

Label



50

BROAD SPECTRUM SPF 50
UVA/UVB PROTECTION
WATER RESISTANT (80 MINUTES)

**Premium Hydrating
Sunscreen Spray**

Paraben Free
Cruelty Free • Vegan

NET WT 6.0 OZ (170g)

A premium SPF sunscreen spray to protect & hydrate your skin while you're out & about in the sun. Enriched with argan & jojoba oils to keep your skin moisturized & protected.



Paraben Free



Cruelty Free



100% Vegan

Drug Facts

Active Ingredients	Purpose
Avobenzene 3%, Homosalate 15%, Octisalate 5%, Octocrylene 10%.....	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 aging caused by the sun.

Warnings

For external use only.

Flammable - Do not use while smoking or near heat or flame.

Do not use on damaged or broken skin.

When using this product • keep out of eyes. Rinse with water to remove.
• keep away from face to avoid breathing it • contents under pressure,
• Do not puncture or incinerate. Do not store at temperature above 120°F.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions • Hold container 4 to 6 inches from the skin to apply • spray liberally and spread evenly by hand 15 minutes before sun exposure • do not spray directly into face. Spray on hands then apply to face • do not apply in windy conditions • use in a well ventilated area. • Reapply: after 80 minutes of swimming or sweating • Immediately after towel drying • At least every 2 hours • children under 6 months: ask a doctor. • **Sun protection measures:** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease risk, regularly use a sunscreen with 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 sleeved shirts, pants, hats, and sunglasses.

Other Information Protect this product from excessive heat and direct sun.

Inactive Ingredients: Alcohol Denat., Acrylates/Octylacrylamide Copolymer, Argania Spinosa Kernel Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Tocopherol, Ascorbic Acid, Glycerin, Caprylic/Capric Triglyceride, Diethylhexyl Syringylidenemalonate, Fragrance

Questions? call 1800-914-3880



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Alexandria, TN. 37012 USA
USA: 1800 914 3880

born in
australia
MADE IN USA

AUSTRALIAN SANDS SPF 50 SUNSCREEN

avobenzene 3%, homosalate 15%, octisalate 5%, octocrylene 10% spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72839-391
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK)	
ARGAN OIL (UNII: 4V59G5UW9X)	
JOJOBA OIL (UNII: 724GKU717M)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-391-06	170 g in 1 CAN; Type 0: Not a Combination Product	10/12/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/12/2022	

Labeler - Derma Care Research Labs, LLC (116817470)

Registrant - Derma Care Research Labs, LLC (116817470)

Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs		116817470	manufacture(72839-391)