BLACK GIRL SUNSCREEN SPF 30- avobenzone 3%, homosalate 15%, octisalate 5%, octocrylene 8% 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.

Active Ingredients

Avobenzone 3%, Homosalate 15%, Octisalate 5%, Octocrylene 8%

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 n 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:

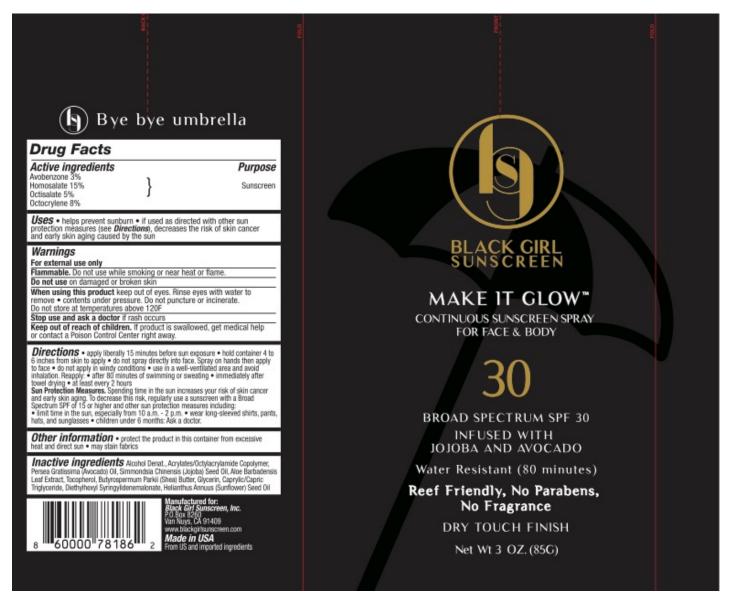
- limit time in the sun, especially from 10 am to 2 pm
- wear long-sleeved shirts, pants, hats, and sunglasses.
- Children under 6 months: ask a doctor.

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 no apply in windy conditions. Use in a well-ventilated area.

Inactive Ingredients

Alcohol Denat., Acrylates/Octylacrylamide Copolymer, Persea Gratissima (Avocado) Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Aloe Barbadensis Leaf Extract, Tocopherol, Butyrospermum Parkii (Shea) Butter, Glycerin, Caprylic/Capric Triglyceride, Diethylhexyl Syringylidenemalonate, Helianthus Annuus (Sunflower) Seed Oil.

Label



avobenzone 3%, homosalate 15%, octisalate 5%, octocrylene 8% spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72839-121	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	15 g in 100 g	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	8 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
GLYCERIN (UNII: PDC6A3C0OX)			
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK)			
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)			
TOCOPHEROL (UNII: ROZB2556P8)			
ALCOHOL (UNII: 3K9958V90M)			
JOJOBA OIL (UNII: 724GKU717M)			
AVOCADO OIL (UNII: 6VNO72PFC1)			
SHEA BUTTER (UNII: K49155WL9Y)			
SUNFLOWER OIL (UNII: 3W1JG795YI)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-121- 03	85 g in 1 CAN; Type 0: Not a Combination Product	01/03/2022	

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/03/2022	

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(72839-121)	

Revised: 12/2021 Derma Care Research Labs, LLC