

SKIN PROUD SERIOUS SHADE SUNSCREEN SPF 50- avobenzone, homosalate, octisalate, octocrylene emulsion
Lottie London Limited

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.

Skin Proud Serious Shade Sunscreen SPF 50

Drug Facts

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.

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 physician

if rash occurs.

Keep out of reach of children.

If product is swallowed get medical help or contact a Poison Control Centre right away.

Directions

- Apply generously and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours. 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 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 a.m.-2 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses.
- For use on children under 6 months of age: Ask a doctor

Other information

- Protect this product from excessive heat and direct sun.
- You may report a serious adverse reaction to this product to Report Reaction, LLC, PO Box 22, Plainsboro, NJ 08536.

Inactive ingredients

Aqua (Water, Eau), Cocoglycerides, Silica, Cetyl Dimethicone, Peg-15 Cocamine, Stearyl Behenate, Glycerin, C12-15 Alkyl Benzoate, Peg-40 Stearate, Polyhydroxystearic Acid, Phenoxyethanol, Tocopheryl Acetate, Caprylyl Glycol, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Parfum (Fragrance), Disodium Edta, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Caprylhydroxamic Acid, Malpighia Punicifolia Fruit Extract, Spirulina Platensis Powder, Aloe Barbadensis Leaf Juice, Cetearyl Alcohol, Sodium Hydroxide, Ceramide Np, Limonene, Hexyl Cinnamal, Linalool, Geraniol, Citral.

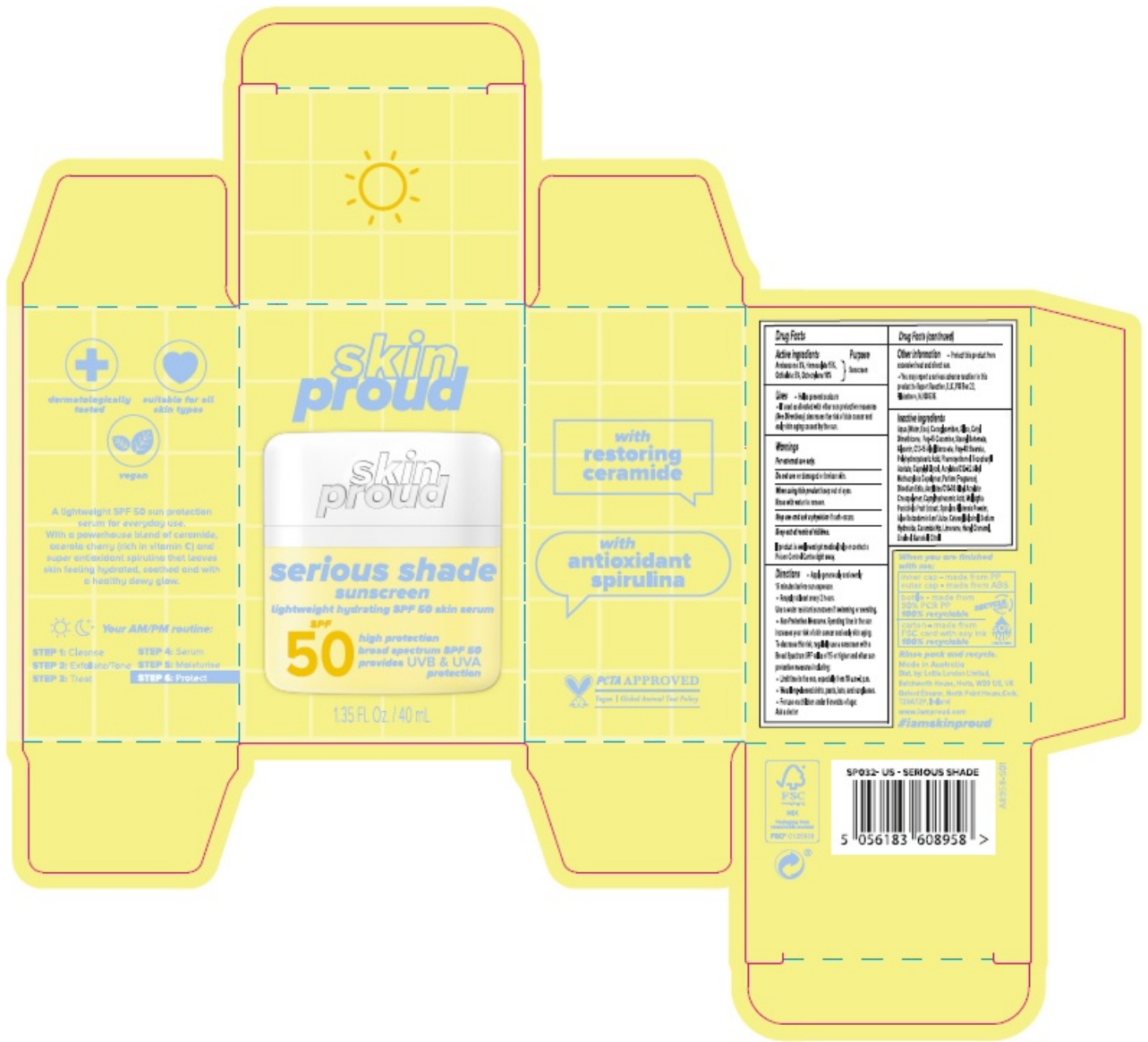
Company Information

Made in Australia

Dist. by: Lottie London Limited, Batchworth House, Herts, WD3 1JE, UK Oxford Eireann, North Point House, Cork, T23AT2P, Ireland

www.iamproud.com

Product Packaging



SKIN PROUD SERIOUS SHADE SUNSCREEN SPF 50

avobenzone, homosalate, octisalate, octocrylene emulsion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:82803-001 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB) | |
| PEG-15 COCAMINE (UNII: 8L6LB12TSJ) | |
| PEG-40 STEARATE (UNII: ECU18C66Q7) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| CERAMIDE NP (UNII: 4370DF050B) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| GERANIOL (UNII: L837108USY) | |
| CITRAL (UNII: T7EU009VPP) | |
| CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) | |
| LIMONENE, (+)- (UNII: GFD7C86Q1W) | |
| .ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I) | |
| LINALOOL, (+)- (UNII: F4VNO44C09) | |
| STEARYL BEHENATE (UNII: A68S9UI39D) | |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | |
| CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W) | |
| MALPIGHIA GLABRA FRUIT (UNII: B94O42LA9M) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| COCO-GLYCERIDES (UNII: ISE9I7DNUG) | |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) | |
| SPIRULINA PLATENSIS (UNII: 9L3TIH1UUE) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:82803-001-01 | 1 in 1 CARTON | 02/27/2023 | |
| 1 | | 40 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | M020 | 02/27/2023 | |

Labeler - Lottie London Limited (220466583)

