

FLESH HYDRATING SPF SERUM- avobenzone, homosalate, octisalate lotion
Revlon Consumer Products Corporation

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.

Flesh Hydrating SPF Serum

Drug Facts

Avobenzone 3.0%

Homosalate 10.0%

Octisalate 5.0%

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 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
- Use a water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours

Other Information

Protect this product from excessive heat and direct sun

Package



FLESH HYDRATING SPF SERUM

avobenzone, homosalate, octisalate lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:10967-660 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 10 mg in 1 mL |
| OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W) | OCTISALATE | 5 mg in 1 mL |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 3 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| GLYCERIN (UNII: PDC6 A3C0 OX) | |
| HONEY (UNII: Y9H1V576 FH) | |
| AMMONIUM ACRYLO YLDIMETHYLTAURATE/BEHENETH-25 METHACRYLATE CROSSPOLYMER (52000 MPA.S) (UNII: LZ29 1VH9 0H) | |

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| CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) |
| UREA (UNII: 8W8T17847W) |
| HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR) |
| LINALOOL, (+)- (UNII: F4VNO44C09) |
| PUNICA GRANATUM ROOT BARK (UNII: CLV243T1D) |
| SODIUM LACTATE (UNII: TU7HW0W0QT) |
| ORNITHINE HYDROCHLORIDE (UNII: HBK84K66XH) |
| TROLAMINE (UNII: 9O3K93S3TK) |
| .ALPHA.-HEXYL CINNAMALDEHYDE (UNII: 7X6O37OK2I) |
| LIMONENE, (+)- (UNII: GFD7C86Q1W) |
| WATER (UNII: 059QF0KO0R) |
| ARGININE HYDROCHLORIDE (UNII: F7LTH1E20Y) |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) |
| HYDROXYACETOPHENONE (UNII: G1L3HT4CMH) |
| DIPROPYLENE GLYCOL (UNII: E107L85C40) |
| LYSINE HYDROCHLORIDE (UNII: JNJ23Q2COM) |
| MALTODEXTRIN (UNII: 7CVR7L4A2D) |
| CHLORPHENESIN (UNII: I670DAL4SZ) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:10967-660-01 | 30 mL in 1 PACKAGE; Type 0: Not a Combination Product | 04/01/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352 | 04/01/2020 | |

Labeler - Revlon Consumer Products Corporation (788820165)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------|---------|-----------|------------------------|
| Englewood Lab, Inc. | | 080366903 | manufacture(10967-660) |

Revised: 4/2020

Revlon Consumer Products Corporation