THE GOOD STUFF AFTERSHAVE SPF 15- avobenzone, octocrylene, and octisalate cream Prime Enterprises Inc.

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.

The Good Stuff After Shave SPF 15

Active Ingredients

Avobenzone 2%

Octisalate 5%

Octocrylene 1.85%

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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
- after 40 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 this risk, regularly use a sunscreen 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
- children under 6 months: Ask a doctor

Inactive Ingredients

Water, Glycerin, C12-15 Alkyl Lactate, Dimethicone, Disodium Lauriminodipropionate Tocopheryl Phosphates, Diisopropyl Adipate, Steareth-2, Aluminum Starch Octenylsuccinate, Octyldodecyl Stearate, Steareth-21, Fragrance, Acrylamide/Sodium Acrylate Copolymer, Mineral Oil, Aloe Barbadensis Leaf Juice, Phenoxyethanol, Trideceth-6, Disodium EDTA, Methylisothiazolinone

Other Information

• protect this product from excessive heat and direct sun

Questions or comments?

• Call toll free 954-525-9209

The Good Stuff After Shave SPF15



THE GOOD STUFF AFTERSHAVE SPF 15 avobenzone, octocrylene, and octisalate cream Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:58443-0198 Route of Administration TOPICAL Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength

| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 20 mg in 1 mL |
|--|-------------|-----------------|
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 18.5 mg in 1 mL |
| OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W) | OCTISALATE | 50 mg in 1 mL |

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA) | |
| DISO DIUM LAURIMINO DIPRO PIO NATE TO CO PHERYL PHO SPHATES (UNII: 0 K5Y9 U1P6 M) | |
| GLYCERIN (UNII: PDC6 A3C0 O X) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| STEARETH-2 (UNII: V56DFE46J5) | |
| STEARETH-21 (UNII: 53J3F32P58) | |
| OCTYLDODECYL STEARATE (UNII: K6F16QGO28) | |
| ALUMINUM STARCH O CTENYLSUCCINATE (UNII: 19 PJ0 O 6 2 9 4) | |
| DIISOPROPYL ADIPATE (UNII: P7E6YFV72X) | |
| DIMETHICO NE (UNII: 92RU3N3Y1O) | |
| TRIDECETH-6 (UNII: 3T5PCR2H0C) | |
| C12-15 ALKYL LACTATE (UNII: GC844VRD7E) | |
| PHENO XYETHANOL (UNII: HIE492ZZ3T) | |
| WATER (UNII: 059QF0KO0R) | |
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X) | |
| EDETATE DISO DIUM (UNII: 7FLD9 1C86K) | |
| SODIUM ACRYLO YLDIMETHYLTAURATE-ACRYLAMIDE COPOLYMER (1:1; 90000-150000 MPA.S) (UNII: 5F4963KLHS) | |

| Product Characteristics | | | |
|-------------------------|-------|--------------|--|
| Color | white | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

| ı | Pac | kaging | | | |
|---|------|-----------------|---|-----------------------------|--------------------|
| ı | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| ı | 1 NI | DC:58443-0198-3 | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/08/2015 | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part352 | 10/08/2015 | |
| | | | |

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

| Establishment | | | |
|------------------------|---------|-----------|--|
| Name | Address | ID/FEI | Business Operations |
| Prime Enterprises Inc. | | 101946028 | pack(58443-0198), manufacture(58443-0198), label(58443-0198) |

Revised: 1/2020 Prime Enterprises Inc.