

**AMERICAN CREW ALL IN ONE FACE BALM BROAD SPECTRUM SPF 15-  
octisalate,homosalate,avobenzone,octocrylene liquid  
Revlon Consumer Products Corp**

*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.*

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**American Crew All in One Face Balm**

**Active Ingredients**

Octisalate 5.0%

Homosalate 5.0%

Avobenzone 2.0%

Octocrylene 2.0%

**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 a 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
- Use a water resistant sunscreen if swimming or sweating
- Reapply 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 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 am - 2 pm
- Wear long-sleeved shirts, pants, hats and sunglasses.

## Inactive Ingredients

Aqua/Water/Eau, C12-15 Alkyl Benzoate, Squalane, Glycerin, Dimethicone, Cetearyl Alcohol, Behentrimonium Chloride, Polyquaternium-37, Bisabolol, Panthenol, Hydroxyacetophenone, Glyceryl Dibehenate, Allantoin, Tocopheryl Acetate, Tribehenin, Glyceryl Behenate, Farnesol, Disodium EDTA, Sodium Citrate, Dipotassium Glycyrrhizate, Dimethicone Crosspolymer, Saccharide Isomerate, Parfum (Fragrance), Caprylyl Glycol, 1,2-Hexanediol, Phenoxyethanol, Hydroxycitronellal,

## Questions ?

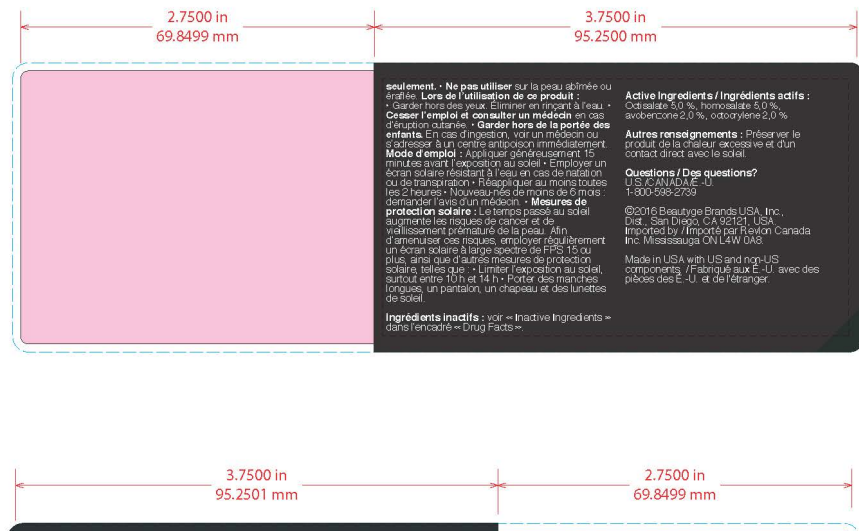
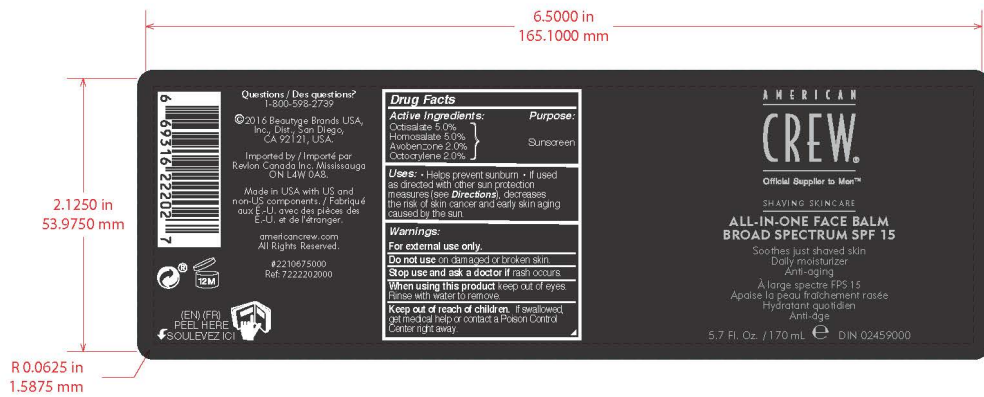
1-800-598-2739

American Crew All in One Face Balm

Broad Spectrum SPF 15

170mL

Supplier: MULTI-COLOR Corporation  
Application: Pressure Sensitive





Job Name: CREW SSC SHAVE BALM LABEL CL1  
 Part Number: 2210675000  
 Color:  Black  
            White Ink  
            Silver Ink  
            Matte Coating  
 Material: Clear Label  
 Countries Sold: USA, Canada  
 Components: Bottle, label, cap  
 Reason for Submission: New Product, Updated directions/claims, claim added, New regulatory information, FR copy added, Logo Updated, TR comments applied, Regulatory Comments applied, Fill Claim Revised  
 Brand Manager Name: Vasthy Villalobos  
 Email Address: vasthy.villalobos@revlon.com  
 Date of Submission: 12/09/16

WEB Direction Copy 3  
 .03125" Copy to Die Holdback  
 .0625" Bleed



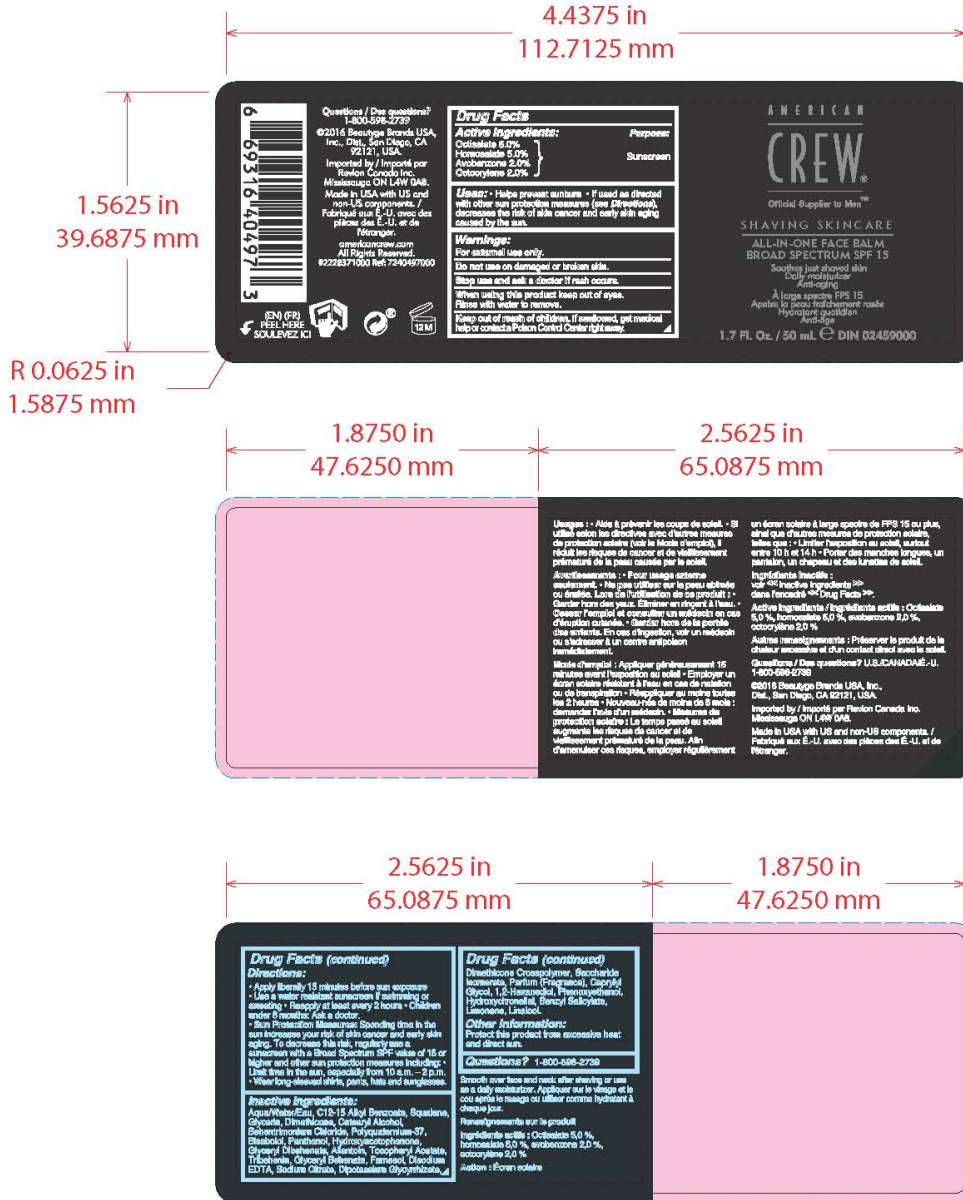
405 Willow Springs Lane  
 York, PA 17406  
 Phone: 717-266-9675  
 1-888-800-YORK (9675)  
 Customer Service Fax: 717-266-9835

|                  |               |
|------------------|---------------|
| Customer: Revlon | Date: 8/19/16 |
| File: RDCT10804  | Drawn by: SMM |

American Crew All in One Face Balm  
 Broad Spectrum SPF 15  
 50mL

Supplier: MULTI-COLOR Corporation  
 Application: Pressure Sensitive

Placeholder information in PINK



WFR Direction Copy 3

Job Name: LBL-WRP-CREW SSC SHV BALM 50ml  
 Part Number: 2228371000  
 Color: ■ PMS 877 Silver Ink  
 ■ Black  
 ■ White Ink  
 ■ UV Satin Varnish  
 Material: Clear BOP  
 Countries Sold: USA, Canada  
 Components: Bottle, Cap and Label  
 Reason for Submission: New Product Size  
 Brand Manager Name: Vasthy Villalobos  
 Email Address: vasthy.villalobos@revlon.com  
 Date of Submission: 11/29/16

ldback



405 Willow Springs Lane  
 York, PA 17406  
 Phone: 717-266-9675  
 1-888-800-YORK (9675)  
 Customer Service Fax: 717-266-9835

AMERICAN CREW ALL IN ONE FACE BALM BROAD SPECTRUM SPF 15

octisalate,homosalate,avobenzone,octocrylene liquid

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:10967-651 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength     |
|--|-------------------|--------------|
| OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)   | OCTISALATE        | 5 mg in 1 mL |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)       | HOMOSALATE        | 5 mg in 1 mL |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)       | AVOBENZONE        | 2 mg in 1 mL |
| OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM) | OCTOCRYLENE       | 2 mg in 1 mL |

## Inactive Ingredients

| Ingredient Name                                     | Strength |
|---|----------|
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)          |          |
| SQUALANE (UNII: GW89575KF9)                         |          |
| GLYCERIN (UNII: PDC6A3C0OX)                         |          |
| DIMETHICONE (UNII: 92RU3N3Y1O)                      |          |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)              |          |
| BEHENTRIMONIUM CHLORIDE (UNII: X7GNG3S47T)          |          |
| POLYQUATERNIUM-37 (10000 MPA.S) (UNII: 41QWS48DFN)  |          |
| .ALPHA.-BISABOLOL, (+/-)- (UNII: 36HQN158VC)        |          |
| DEXPANTHENOL (UNII: 1O6C93RI7Z)                     |          |
| 4-HYDROXY ACETOPHENONE (UNII: G1L3HT4CMH)           |          |
| GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)              |          |
| ALLANTOIN (UNII: 344S277G0Z)                        |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                  |          |
| 1,2-HEXANEDIOL (UNII: TR046Y3K1G)                   |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)       |          |
| TRIBEHENIN (UNII: 8OC9U7TQZ0)                       |          |
| FARNESOL (UNII: EB41QIU6JL)                         |          |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)       |          |
| SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) |          |
| GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)     |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                   |          |
| SACCHARIDE ISOMERATE (UNII: W8K377W98I)             |          |
| HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)               |          |
| BENZYL SALICYLATE (UNII: WAO5MKN9TU)                |          |
| LIMONENE, (+)- (UNII: GFD7C86Q1W)                   |          |
| LINALOOL, (+/-)- (UNII: D81QY6I88E)                 |          |
| .BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)         |          |
| EUGENOL (UNII: 3T8H1794QW)                          |          |
| GERANIOL (UNII: L837108USY)                         |          |
| BENZYL BENZOATE (UNII: N863NB338G)                  |          |
| CITRAL (UNII: T7EU0O9VPP)                           |          |

CINNAMYL ALCOHOL (UNII: SS8YOP444F)

### Packaging

| # | Item Code        | Package Description                                    | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:10967-651-51 | 170 mL in 1 PACKAGE; Type 0: Not a Combination Product | 04/01/2017           |                    |
| 2 | NDC:10967-651-24 | 50 mL in 1 PACKAGE; Type 0: Not a Combination Product  | 04/01/2017           |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352                                  | 04/01/2017           |                    |

**Labeler** - Revlon Consumer Products Corp (788820165)

### Establishment

| Name         | Address | ID/FEI    | Business Operations    |
|--------------|---------|-----------|------------------------|
| REVLON, INC. |         | 809725570 | manufacture(10967-651) |

Revised: 11/2019

Revlon Consumer Products Corp