**ULTRA VIOLETTE SUPREME SCREEN BROAD SPECTRUM SPF 50-avobenzone,homosalate,octisalate,octocrylene cream**
**Grace and Fire USA Inc.**

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## ACTIVE INGREDIENTS

AVOBENZONE 3.0%
HOMOSALATE 7.0%
OCTISALATE 5.0%
OCTOCRYLENE 8.0%

## PURPOSE

SUNSCREEN

## USE

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

## 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
- 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
- children under 6 months of age: Ask a doctor

## Inactive Ingredients

Water, Alcohol Denat., Butylene Glycol, Diisopropyl Adipate, Glycerin, Cetearyl Alcohol, Caprylyl Methicone, Isododecane, Copernicia Cerifera (Camauba) Wax, Oryza Saliva (Rice) Bran Wax, Polysorbate 60, Dimethicone, Ceteareth-20, Nylon- 6/12, Saccharide Isomerate, Squalane, Camosine, Tocopheryl Acetate, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Silica, PEG-40 Stearate, Citric Acid, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Glyceryl Caprylate, Fragrance, Disodium EDTA, Pentylene Glycol, Caprylhydroxamic Acid, Triethanolamine, Lactic Acid, Sorbitan Isostearate, Sodium Citrate, Iron Oxides (CI 77491), Iron Oxides (CI 77492), Iron Oxides (CI 77499).

## Other Information

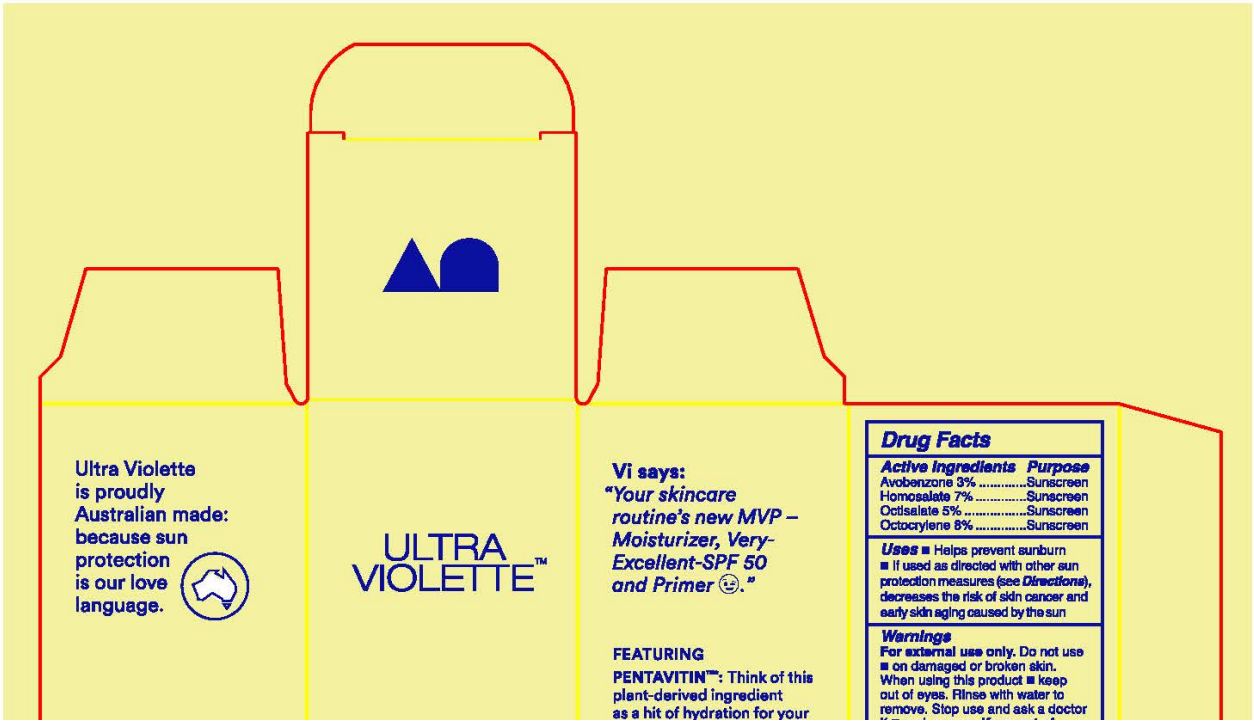
protect this product from excessive heat and direct sun

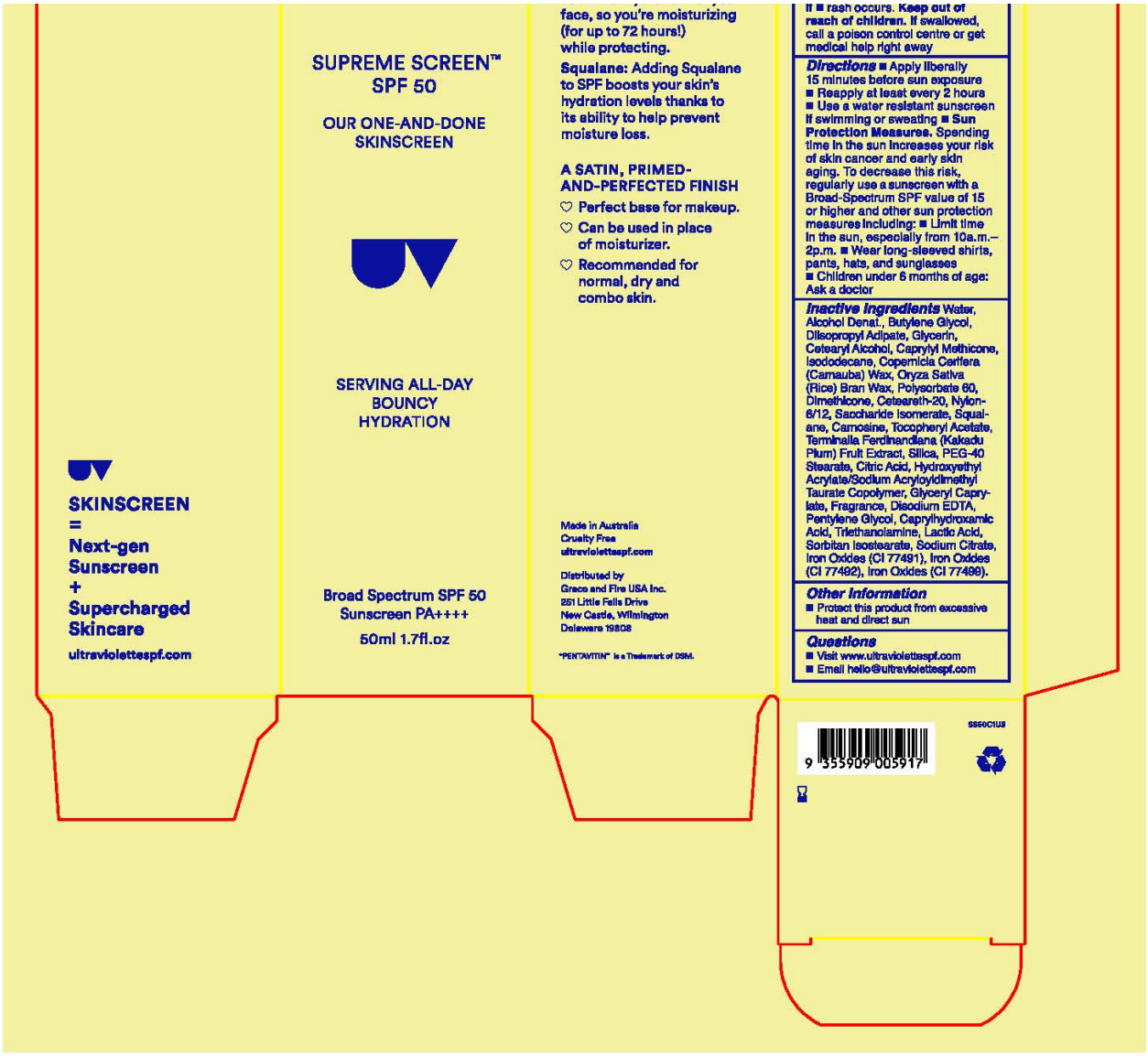
## PRINCIPAL DISPLAY PANEL

SUPREME SCREEN 50ML USA
CARTON – NEW DIELINE
SS50C1US – FA2

PANTONE 917C

PANTONE Blue 072C






Ultra Violette

Supreme Screen Broad Spectrum SPF 50

1.7 FL. OZ. (50 mL)

# ULTRA VIOLETTE SUPREME SCREEN BROAD SPECTRUM SPF 50

avobenzone,homosalate,octisalate,octocrylene cream

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:84803-100 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **HOMOSALATE** (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 70 mg in 1 mL |

| | | |
|---|---|---|
| **AVOBENZONE** (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 30 mg in 1 mL |
| **OCTISALATE** (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 50 mg in 1 mL |
| **OCTOCRYLENE** (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 80 mg in 1 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **CITRIC ACID MONOHYDRATE** (UNII: 2968PHW8QP) | |
| **CAPRYLHYDROXAMIC ACID** (UNII: UPY805K99W) | |
| **SODIUM CITRATE** (UNII: 1Q73Q2JULR) | |
| **PENTYLENE GLYCOL** (UNII: 50C1307PZG) | |
| **LACTIC ACID** (UNII: 33X04XA5AT) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **DIMETHICONE, UNSPECIFIED** (UNII: 92RU3N3Y1O) | |
| **CAPRYLYL TRISILOXANE** (UNII: Q95M2P1KJL) | |
| **CETOSTEARYL ALCOHOL** (UNII: 2DMT128M1S) | |
| **KAKADU PLUM** (UNII: 0ZQ1D2FDLI) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SQUALANE** (UNII: GW89575KF9) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **GLYCERYL CAPRYLATE** (UNII: TM2TZD4G4A) | |
| **SORBITAN ISOSTEARATE** (UNII: 01S2G2C1E4) | |
| **FERROSOFERRIC OXIDE** (UNII: XM0M87F357) | |
| **DIISOPROPYL ADIPATE** (UNII: P7E6YFV72X) | |
| **ALCOHOL** (UNII: 3K9958V90M) | |
| **BUTYLENE GLYCOL** (UNII: 3XUS85K0RA) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **ISODODECANE** (UNII: A8289P68Y2) | |
| **RICE BRAN** (UNII: R60QEP13IC) | |
| **POLYSORBATE 60** (UNII: CAL22UVI4M) | |
| **POLYOXYL 20 CETOSTEARYL ETHER** (UNII: YRC528SWJY) | |
| **NYLON-12** (UNII: 446U8J075B) | |
| **SACCHARIDE ISOMERATE** (UNII: W8K377W98I) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **CARNOSINE** (UNII: 8HO6PVN24W) | |
| **PEG-40 MONOSTEARATE** (UNII: ECU18C66Q7) | |
| **HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%)** (UNII: 86FQE96TZ4) | |
| **TROLAMINE** (UNII: 9O3K93S3TK) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:84803-100-50 | 50 mL in 1 TUBE; Type 0: Not a Combination Product | 12/01/2024 | |
| **2** | NDC:84803-100-15 | 15 mL in 1 TUBE; Type 0: Not a Combination Product | 12/01/2024 | |

| | | | | |
|---|---|---|---|---|
| **3** | NDC:84803-100-05 | 5 mL in 1 TUBE; Type 0: Not a Combination Product | 12/01/2024 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M020 | 12/01/2024 | |

## Labeler - Grace and Fire USA Inc. (119357605)

Revised: 11/2024 Grace and Fire USA Inc.