# SPORT SUNSCREEN SPF 50 TOPCARE- homosalate 6.00% octinoxate 7.50% octisalate 5.00% octocrylene 10.00% zinc oxide 8.00% stick TopCo

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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#### **Drug Facts**

| Active ingredients | Purpose   |
|--------------------|-----------|
| Homosalate 6.0%    | Sunscreen |
| Octinoxate 7.5%    | Sunscreen |
| Octisalate 5.0%    | Sunscreen |
| Octocrylene 10.0%  | Sunscreen |
| Zinc Oxide 8.0%    |           |

**Uses** • helps prevent sunburn • higher SPF gives more sunburn protection • retains SPF after 40 minutes of activity in the water • provides high protection against sunburn

### 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. • 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 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

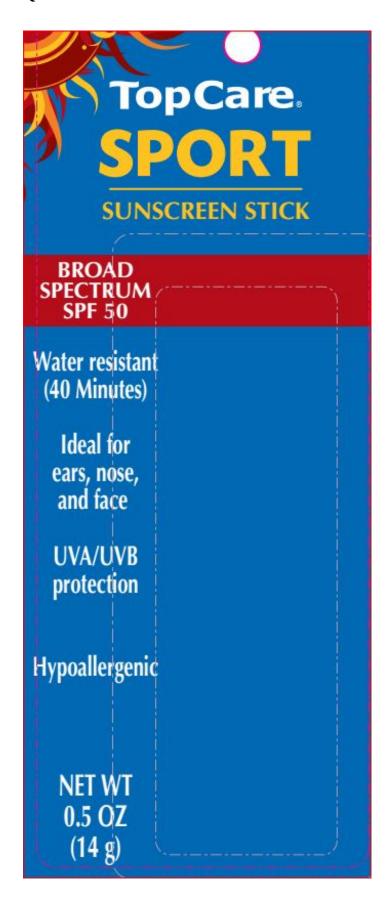
**Other information** • protect the product in this container from excessive heat and direct sun

#### **Inactive ingredients**

Aloe Barbadensis Leaf Extract, C12-15 Alkyl Benzoate, Ceresin, Chamomilla Recutita (Matricaria) Flower Extract, Copernicia Cerifera (Carnauba) Wax, Dimethicone, Ethyl Macadamiate, Ethylhexyl Palmitate, Helianthus Annuus (Sunflower) Seed Oil, Hydrogenated Polyisobutene, Malic Acid, Mentha Piperita (Peppermint) Oil, Octyldodecanol, Polyethylene, Propylparaben, Retinyl Palmitate, Sorbitan Sesquioleate,

Tocopherol, Tocopheryl Acetate, Triethoxycaprylylsilane.

## Questions? 1-888-423-0139



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#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-865

| Active Ingredient/Active Moiety                                |                   |                |  |
|----------------------------------------------------------------|-------------------|----------------|--|
| Ingredient Name                                                | Basis of Strength | Strength       |  |
| Homosalate (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)   | Ho mo sa la te    | 6 g in 100 g   |  |
| Octinoxate (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)   | Octinoxate        | 7.5 g in 100 g |  |
| Octisalate (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W) | Octisalate        | 5 g in 100 g   |  |
| Octocrylene (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | Octocrylene       | 10 g in 100 g  |  |
| Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)  | ZINC CATION       | 8 g in 100 g   |  |

| Inactive Ingredients                         |          |  |  |
|----------------------------------------------|----------|--|--|
| Ingredient Name                              | Strength |  |  |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)            |          |  |  |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)   |          |  |  |
| Ceresin (UNII: Q1LS2UJO3A)                   |          |  |  |
| CHAMO MILE (UNII: FGL3685T2X)                |          |  |  |
| CARNAUBA WAX (UNII: R12CBM0EIZ)              |          |  |  |
| Dimethicone (UNII: 92RU3N3Y1O)               |          |  |  |
| Ethyl Macadamiate (UNII: ANA2NCS6V1)         |          |  |  |
| Ethylhexyl Palmitate (UNII: 2865993309)      |          |  |  |
| SUNFLOWER OIL (UNII: 3W1JG795YI)             |          |  |  |
| Malic Acid (UNII: 817L1N4CKP)                |          |  |  |
| PEPPERMINT OIL (UNII: AV092KU4JH)            |          |  |  |
| Octyldodecanol (UNII: 461N1O614Y)            |          |  |  |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) |          |  |  |
| Propylparaben (UNII: Z8IX2SC1OH)             |          |  |  |
| VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)       |          |  |  |
| Sorbitan Sesquioleate (UNII: 0 W8 RRI5W5A)   |          |  |  |
| TOCOPHEROL (UNII: R0 ZB2556 P8)              |          |  |  |
| .ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0) |          |  |  |
| Triethoxycaprylylsilane (UNII: LDC331P08E)   |          |  |  |

|   | Packaging |                 |                                                        |                             |                    |
|---|-----------|-----------------|--------------------------------------------------------|-----------------------------|--------------------|
| l | #         | Item Code       | Package Description                                    | <b>Marketing Start Date</b> | Marketing End Date |
| l | 1 NI      | DC:36800-865-01 | 14 g in 1 CONTAINER; Type 0: Not a Combination Product | 0 1/25/20 13                |                    |

| Marketing Information   |                                          |                      |                    |
|-------------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part352                                  | 0 1/25/20 13         |                    |
|                         |                                          |                      |                    |

# **Labeler -** TopCo (006935977)

# Registrant - Product Quest (927768135)

| Establishment |         |           |                        |
|---------------|---------|-----------|------------------------|
| Name          | Address | ID/FEI    | Business Operations    |
| Product Quest |         | 927768135 | manufacture(36800-865) |

Revised: 5/2018 TopCo