SUNSCREEN- homosalate, octocrylene, octisalate, avobenzone gel Oxygen Development, LLC

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.

Broad Spectrum Sunscreen Clear as Day SPF 46 Starface

Active ingredient

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 10%

Uses

Helps prevent sunburn. If used as directed with another sun protection measures (see Directions), decreasses the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only. Do not use on damage or broken skin. When using this product, keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center rigth away

Directions

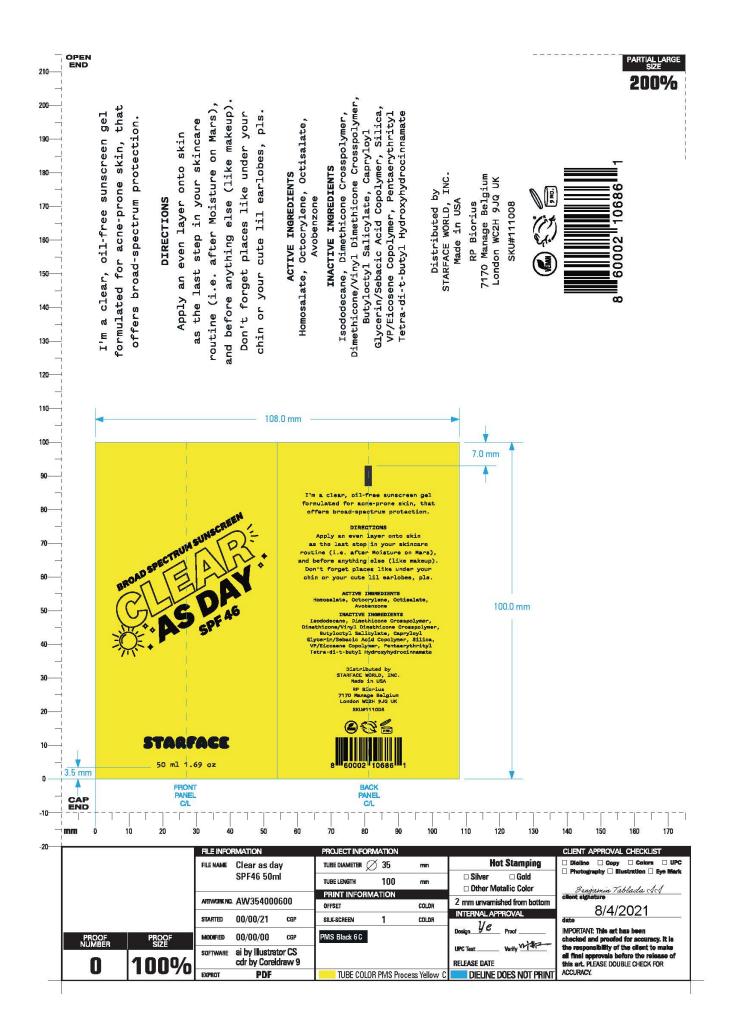
Apply liberally 15 minutes before sun exposure. Reapply after 80 minutes of swimming or sweating. Reapply at least every 2 hours.

Sun protection meassures: Spending time in the sun increasses 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, specially from 10 am - 2 pm, wear long-sleeved shirts, pants, hats and sunglasses.

Inactive ingredients

Isododecane, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Butyloctyl Salicylate, Capryloyl Glycerin/Sebacic Acid Copolymer, Silica, VP/Eicosene Copolymer, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate

Package



Package





Utah Paper Box Electronic Die Pattern

| Customer: | STARFACE |
|--------------|-------------------------|
| Project: | Starface Tube Carton |
| Sales Rep: | Sharon Eucce |
| Designer: | Mario Murga |
| Design Side: | printed |
| Date: | 07/13/2021 |
| Dimension: | 1+3/4 x 1+3/4 x 5+25/32 |
| Blank Size: | 10+13/16 x 7+3/4 |
| Stock: | SBS .018 |
| Style: | Same Tuck Ends |
| File Name: | 10407_01.ARD |

Do Not Modify Die Pattern

Specific Rule Legend Cut

Doc: IMSP 8.3.5-02 Rev:0 Approval: Pre-Prod Op Mgr Eff: 4-1-16

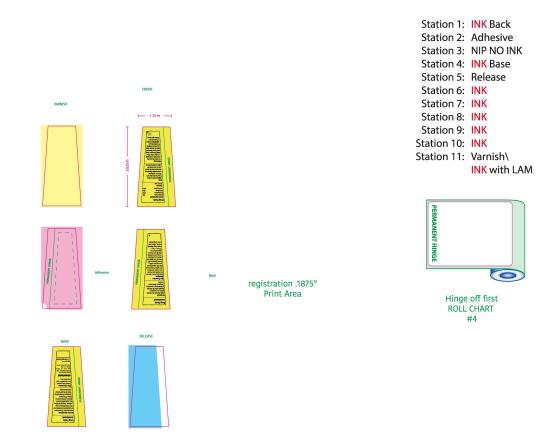
Package

SKIN CANCER FOUNDATION SEAL





WHITE: CMYK 0, 0, 0, 0



| SUNSCREEN | | | | | |
|--|---------------------------|------------|------------------------|-----------------|--|
| homosalate, octocrylene, octisalate, avobenzone gel | | | | | |
| | | | | | |
| Product Information | Product Information | | | | |
| Product Type | HUMAN OTC DRUG | Item Code | (Source) | NDC:61354-047 | |
| Route of Administration | TOPICAL | | | | |
| | | | | | |
| | | | | | |
| Active Ingredient/Active Moiety | | | | | |
| Ingred | lient Name | | Basis of Streng | th Strength | |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | | | OCTISALATE | 5 mg in 100 mg | |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | | | HOMOSALATE | 10 mg in 100 mg | |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | | | AVOBENZONE | 3 mg in 100 mg | |
| OCTOCRYLENE (UNII: 5A68WGF6W | M) (OCTOCRYLENE - UNII:5/ | A68WGF6WM) | OCTOCRYLENE | 10 mg in 100 mg | |
| | | | | | |
| | | | | | |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------------|
| ISODODECANE (UNII: A8289P68Y2) | 49.8 mg in 100 mg |
| CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T) | 2 mg in 100 mg |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) | 2.85 mg in 100 mg |
| VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3) | 1.25 mg in 100 mg |
| BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3) | 2 mg in 100 mg |
| DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6) | 12.46 mg in 100 mg |
| ALUMINUM HEXAFLUOROSILICATE NONAHYDRATE (UNII: L5630XRC87) | 1.5 mg in 100 mg |

Packaging

| • 04 | C:61354-047- | 1 in 1 PACKAGE | 02/14/2022 | |
|-------------|--------------|---|------------|--|
| - NDC | | | 02/14/2022 | |
| 1 03 | C:61354-047- | 1 in 1 CARTON | | |
| 1 NDC 02 | C:61354-047- | 1 in 1 PACKAGE | | |
| 1 NDC 01 | | 100 mg in 1 TUBE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part352 | 02/14/2022 | |

Labeler - Oxygen Development, LLC (137098492)

| Establishment | | | | | |
|-------------------------|---------|-----------|------------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| Oxygen Development, LLC | | 137098492 | manufacture(61354-047) | | |

Revised: 2/2023

Oxygen Development, LLC