# (RE)SETTING REFRESHING MIST SPF 40- avobenzone, homosalate, octisalate, octocrylene spray Supergoop, 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.

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#### (Re)Setting Refreshing Mist SPF 40

Active ingredients Purpose

Avobenzone 2.9% Sunscreen

Homosalate 9.8% Sunscreen

Octisalate 4.9% Sunscreen

Octocrylene 9.5% Sunscreen

- 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

#### Keep out of reach of children

If product is swallowed, get medical help or contact a poison Control Center right away

Stop use and ask a doctor if rash occurs

#### 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.

- Apply generously and evenly 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 your 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:

Alcohol Denat., Bisabolol, Brassica Camprestris/Aleurites Fordi Oil Copolymer, Butyloctyl

Salicylate, Caprylic/Capric Triglyceride, Capryloyl Glycerin/Sebacic Acid Copolymer, Dicaprylyl Carbonate, Diethylhexyl Syringylidenemalonate, Diheptyl Succinate, Diisooctyl Succinate, Ethyl Ferulate, Isododecane, Lauroyl Lysine, Mentha Piperita (Peppermint) Oil, Mentha Viridis (Spearmint) Leaf Oil, Nylon-12, PVP, Rosemarinus Officinalis (Rosemary) Leaf Oil, Silica Caprylyl Silylate

Supergoop!

(Re) Setting Refreshing Mist

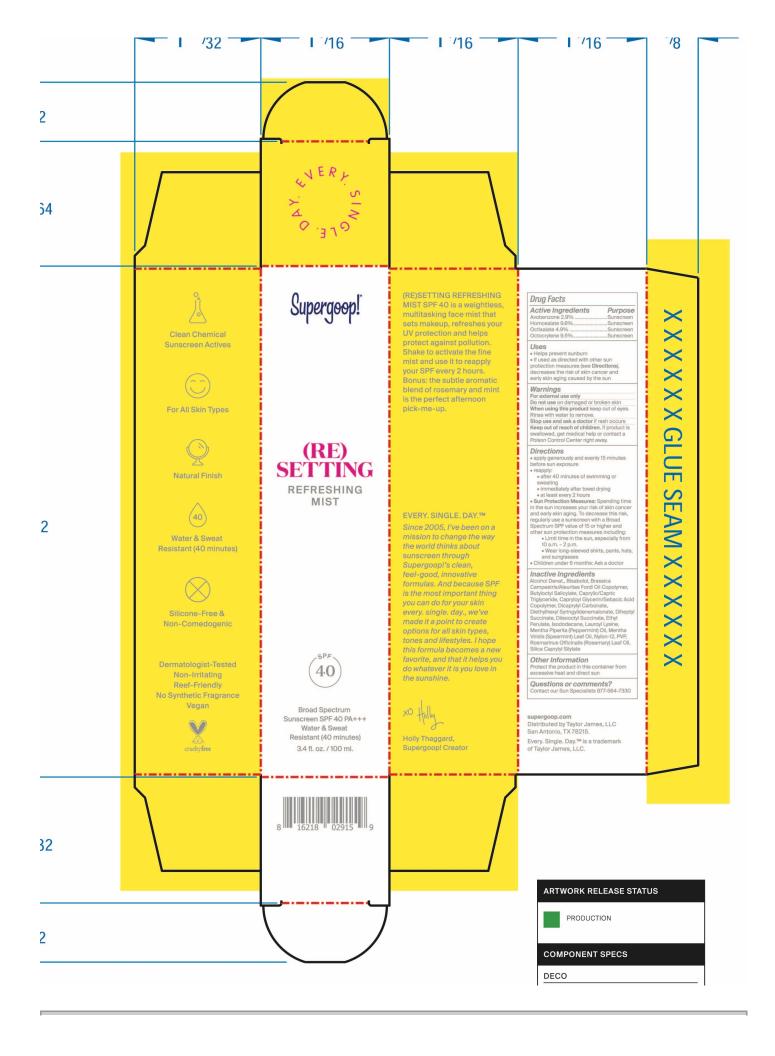
**SPF 40** 

**Broad Spectrum** 

Sunscreen SPF 40 PA+++

Water & Sweat Resistant (40 minutes)

3.4 fl. oz. / 100 ml.



### (RE)SETTING REFRESHING MIST SPF 40

avobenzone, homosalate, octisalate, octocrylene spray

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:75936-361 |
| Route of Administration | TOPICAL        |                    |               |

| Active Ingredient/Active Moiety                                |                          |                 |  |
|--|--------------------------|-----------------|--|
| Ingredient Name  | <b>Basis of Strength</b> | Strength        |  |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)   | AVOBENZ ONE              | 2.9 g in 100 mL |  |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)   | HOMOSALATE               | 9.8 g in 100 mL |  |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE              | 9.5 g in 100 mL |  |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)   | OCTISALATE               | 4.9 g in 100 mL |  |

| Inactive Ingredients  |          |  |  |
|---|----------|--|--|
| Ingredient Name   | Strength |  |  |
| ALCOHOL (UNII: 3K9958V90M)  |          |  |  |
| DIHEPTYL SUCCINATE (UNII: 057N7SS26Y)                                     |          |  |  |
| LEVOMENOL (UNII: 24WE03BX2T)  |          |  |  |
| BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)                                  |          |  |  |
| ETHYL FERULATE (UNII: 5B8915UELW)   |          |  |  |
| LAUROYL LYSINE (UNII: 113171Q70B)   |          |  |  |
| DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)                     |          |  |  |
| SPEARMINT OIL (UNII: C3M81465G5)  |          |  |  |
| ROSEMARY OIL (UNII: 8LGU7VM393)   |          |  |  |
| <b>NYLON-12</b> (UNII: 446U8J075B)  |          |  |  |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                             |          |  |  |
| POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)                                 |          |  |  |
| PEPPERMINT OIL (UNII: AV092KU4JH)   |          |  |  |
| CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T) |          |  |  |
| DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)                                   |          |  |  |
| ISODODECANE (UNII: A8289P68Y2)  |          |  |  |

| l | Packaging |           |   |                         |                       |
|---|-----------|-----------|---|-------------------------|-----------------------|
|   | #         | Item Code | Package Description                                   | Marketing Start<br>Date | Marketing End<br>Date |
|   | 1         |           | 30 mL in 1 BOTTLE; Type 0: Not a Combination Product  | 01/05/2022              |                       |
|   | 2         |           | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | 01/05/2022              |                       |

| Marketing Information |                                 |                 |               |
|-----------------------|---------------------------------|-----------------|---------------|
| Marketing             | Application Number or Monograph | Marketing Start | Marketing End |
| Category              | Citation                        | Date            | Date          |

| OTC monograph final | part352 | 01/05/2022 |
|---------------------|---------|------------|
|                     |         |            |

## Labeler - Supergoop, LLC (117061743)

| Establishment                        |         |           |                            |
|--------------------------------------|---------|-----------|----------------------------|
| Name                                 | Address | ID/FEI    | <b>Business Operations</b> |
| Bell International Laboratories, Inc |         | 967781555 | manufacture(75936-361)     |

Revised: 10/2022 Supergoop, LLC