COOLA CLASSIC BODY SPF 50 GUAVA MANGO- avobenzone, homosalate, octisalate, octocrylene spray COOLA, 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.

Coola Classic Body Spray SPF 50 - Guava Mango

Avobenzone - 2.9%

Homosalate - 4.0%

Octisalate - 4.9% Octocrylene - 9.5%

Sunscreen

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (see Directions), decreases the nsk of skin cancer and early skin aging caused by the sun
- For external use only
- **Flammable:** Contents under pressure. Do not puncture or incinerat. Do not store at temperatures above 120 F. Do not use in the presence of a flame or spark, or while smoking.
- **Do not use** on damaged or broken skin.
- When using this product keep away from face to avoid breathing. Keep out of eyes. Rinse with water to remove. Apply outdoors. Avoid overspray as it could cause surface to become slippery. Do not apply in windy conditions. Use in a well-ventilated area.
- Stop use and ask a doctor if rash occurs.

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Shake Well
- Apply liberally 15 minutes before sun exposure.
- Hold container 4 to 6 inches from skin to apply.
- Rub in. Do not spray directly on face.
- Spray onto hands and apply to face.
- Reapply: After 80 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 six months: Ask a doctor.

Alcohol (ORGANIC), Butyloctyl Salicylate, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Limnanthes Alba (Meadowfoam) Seed Oil, Mauritia Flexuosa (Buriti) Fruit Oil (ORGANIC), Rubus Idaeus (Raspberry) Seed Oil (ORGANIC), Brassica Campestris (Rapeseed) Seed Oil, Carthamus Tinctorius (Safflower) Seed Oil (ORGANIC), Opuntia Ficus-Indica Flower Extract, Camelina Sativa Seed Oil, Ethyl Ferulate, Flavor (Natural)

- May stain fabrics
- Protect this product from excessive heat and direct sun

Call 760-940-2125



COOLA CLASSIC BODY SPF 50 GUAVA MANGO

avobenzone, homosalate, octisalate, octocrylene spray

| Product Information | | | | | |
|-------------------------|----------------|--------------------|---------------|--|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:79753-059 | | |
| Route of Administration | TOPICAL | | | | |
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| | | | | | |

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| VOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZ ONE | 2.9 g in 100 ml |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) OCTISALATE | | 4.9 g in 100 ml |
| CTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 9.5 g in 100 ml |
| IOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 4 g in 100 mL |
| | | |
| nactive Ingredients | | |
| Ingredient Name | | Strength |
| PUNTIA FICUS-INDICA FLOWER (UNII: 83YSP51SMA) | | |
| VINYL ACETATE (UNII: L9MK238N77) | | |
| DIBUTYL MALEATE (UNII: 4X371TMK9K) | | |
| SOBORNYL ACRYLATE (UNII: IX0PRH184P) | | |
| THYL FERULATE (UNII: 5B8915UELW) | | |
| ASPBERRY SEED OIL (UNII: 9S8867952A) | | |
| RASSICA RAPA SUBSP. OLEIFERA OIL (UNII: N4G8379626) | | |
| AMELINA SATIVA SEED OIL (UNII: 12824X01L0) | | |
| LCOHOL (UNII: 3K9958V90M) | | |
| UTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3) | | |
| AFFLOWER OIL (UNII: 65UEH262IS) | | |
| IEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y) | | |
| | | |

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|----------------------|---|-------------------------|-----------------------|
| 1 | NDC:79753-059- 01 | 177 mL in 1 CAN; Type 0: Not a Combination Product | 10/01/2019 | |
| | | 60 mL in 1 CAN; Type 0: Not a Combination Product | 02/01/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------|---|-------------------------|-----------------------|
| OTC monograph final | M020 | 10/01/2019 | |
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Labeler - COOLA, LLC (956990290)

Revised: 11/2022

COOLA, LLC