

CAROLS DAUGHTER MONOI SUNSCREEN BROAD SPECTRUM SPF 30- avobenzone, homosalate, octisalate and octocrylene spray
L'Oreal USA Products Inc

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.

Drug Facts

Active ingredients

Avobenzone 3%

Homosalate 8.8%

Octisalate 4.9%

Octocrylene 5.9%

Purpose

Sunscreen

Uses

- 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

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.
- keep away from face to avoid breathing it

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

For sunscreen use:

- spray liberally and spread evenly by hand 15 minutes before sun exposure
- hold container 4 to 6 inches from the skin to apply
- do not spray directly into face. Spray on hands then apply to face.
- do not apply in windy conditions
- use in a well-ventilated area
- 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

Other information

protect the product in this container from excessive heat and direct sun

Inactive ingredients

isopropyl myristate, caprylic/capric triglyceride, dicaprylyl ether, C12-15 alkyl benzoate, olea europaea (olive) fruit oil, sorbitan trioleate, ethylhexyl palmitate, dimethicone, fragrance, cocos nucifera (coconut) oil, tocopherol, hydroxypalmitoyl sphinganine, hydroxycitronellal, eugenol, limonene, pentaerythrityl tetra-di-t-butyl hydroxyhydroxycinnamate, benzyl salicylate, benzyl alcohol, benzyl benzoate, linalool, capryloyl salicylic acid, alpha-isomethyl ionone, acrylates/dimethicone copolymer, sorbitan oleate, sorbitan laurate, gardenia taitensis flower, geraniol, myristyl malate phosphonic acid

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FORMULA # 999145/2

F.I.L. #D216576/1

Made with love. 

Questions or comments? 1-877-540-2101
Monday-Friday (9 a.m. – 5:30 p.m. EST)
Made in USA of US and/or Imported Ingredients |
Carol's Daughter Products, LLC | New York, NY 10001
carolsdaughter.com



No Mineral Oil No Petrolatum

THE MONOI STORY

"From mother to daughter, for thousands of years, Monoi Oil has been the Tahitian beauty secret. This precious recipe is a sacred ritual, blending together fragrant Tiare Gardenia Flowers and Coprah Coconut Oil. So, just as the beauty secret has been passed down from mother to daughter for generations, I am passing it down to you."

Love,

Lisa

Carol's Daughter

THE SECRET BEHIND A HEALTHY-LOOKING GLOW

We all want beautiful skin that looks and feels incredible to the touch. So start protecting and nourishing all over with this lightweight broad spectrum SPF 30 sunscreen oil. Its recipe infused with a blend of oils helps nourish and soften skin, leaving it with a beautiful looking glow.

Application:

Spray directly onto skin or into hands and smooth evenly all over your body.

For sunscreen benefits, apply 15 minutes prior to sun exposure.

Dermatologist tested for safety
Suitable for sensitive and dry skin types
Non-Greasy

Carol's Daughter

MONOI

Sunscreen Spray
Broad Spectrum
SPF 30

Body Oil Blend
with monoi
and olive oil

Suitable for sensitive
and dry skin types

5.0 FL OZ (148ml)

CAROLS DAUGHTER MONOI SUNSCREEN BROAD SPECTRUM SPF 30

avobenzone, homosalate, octisalate and octocrylene spray

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:49967-398 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 30 mg in 1 mL |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 88 mg in 1 mL |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 49 mg in 1 mL |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 59 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| DICAPRYLYL ETHER (UNII: 77JZM5516Z) | |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | |
| OLIVE OIL (UNII: 6UYK2W1W1E) | |
| SORBITAN TRIOLEATE (UNII: QE6F49RPJ1) | |
| ETHYLHEXYL PALMITATE (UNII: 2865993309) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| COCONUT OIL (UNII: Q9L0O73W7L) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| HYDROXYPALMITOYL SPHINGANINE (UNII: NR33W2353T) | |
| HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR) | |
| EUGENOL (UNII: 3T8H1794QW) | |
| LIMONENE, (+)- (UNII: GFD7C86Q1W) | |
| PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS) | |
| BENZYL SALICYLATE (UNII: WAO5MKN9TU) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| BENZYL BENZOATE (UNII: N863NB338G) | |
| LINALOOL, (+/-)- (UNII: D81QY6I88E) | |
| CAPRYLOYL SALICYLIC ACID (UNII: 5F7PJF6AA4) | |
| ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B) | |
| SORBITAN MONOLEATE (UNII: 06XEA2VD56) | |
| SORBITAN MONOLAURATE (UNII: 6W9PS8B71J) | |
| GARDENIA TAITENSIS FLOWER (UNII: T0OCU8201Y) | |
| GERANIOL (UNII: L837108USY) | |
| MYRISTYL MALATE PHOSPHONIC ACID (UNII: M1533CYO51) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:49967-398-01 | 1 in 1 CARTON | 03/16/2018 | |
| 1 | | 148 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 03/16/2018 | |

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------|---------|-----------|------------------------|
| L'Oreal USA, Inc. | | 624244349 | manufacture(49967-398) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------------|---------|-----------|------------------------|
| Dimensional Merchandising Inc. | | 076693183 | manufacture(49967-398) |

Revised: 3/2018

L'Oreal USA Products Inc