

**COOLA CLASSIC FACE SUNSCREEN CUCUMBER BROAD SPECTRUM SPF 30-
avobenzene homosalate octisalate octocrylene lotion
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 FACE SUNSCREEN Cucumber Broad Spectrum SPF 30

DRUG FACTS

Active Ingredients

Avobenzene 1.75% Homosalate 2.5%
Octisalate 1.5% Octocrylene 3.75%

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.

Stop use and ask 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

- 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 of 15 or higher and after sun protection measures including:
 - limit time in the sun, especially from 10 a.m. – 2 p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses.
- Children under 6 months: Ask a doctor

Inactive Ingredients

Aloe Barbadensis Leaf Juice (ORGANIC), Amyris Balsamifera Bark Oil*, Brassica Campestris (Rapeseed) Seed Oil, Butylene Glycol, Camelina Sativa Seed Oil, Caprylyl Glycol, Carthamus Tinctorius (Safflower) Oleosomes, Carthamus Tinctorius (Safflower) Seed Oil (ORGANIC), Cetearyl Alcohol, Cetyl Palmitate, Citric Acid, Citronellyl Acetate*, Citrus Aurantium Dulcis (Orange) Peel Oil*, Decanal*, Decyl Glucoside, Dimethicone, Dimethyl Heptenol*, Glycerin (ORGANIC), 1,2-Hexanediol, 3-Hexenol*, Hexenyl Acetate*, Hexyl Acetate*, Hydrolyzed Jojoba Esters, Jojoba Esters, Limnanthes Alba (Meadowfoam) Seed Oil, Linalyl Acetate*, Mauritia Flexuosa (Buriti) Fruit Oil, Methyl Dihydroabietate, Nerol*, Opuntia Ficus-Indica Flower Extract, Polyacrylate, Crosspolymer-6, Polysilicone-11, Rubus Idaeus (Raspberry) Seed Oil, Silica, Sodium Phytate, Sorbitan Oleate, Sorbitan Palmitate, Squalane, Triethyl Citrate*, Tropolone, Water, Xanthan Gum

Other Information

- protect this product from excessive heat and direct sun

Questions or Comments? Call 760-940-2125

Package Label - COOLA CLASSIC FACE SUNSCREEN Cucumber Broad Spectrum SPF 30

NEEDS OUTER BOX LABELING INSERTED

SPF

30

70% +

Organic

COOLA®

Classic

Face Sunscreen

Cucumber

Non-Greasy

Ultralight Hydration

+Plant Protection®

Broad Spectrum SPF 30

Water Resistant (40 Minutes)

.85 FL OZ / 25 mL

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Box TO DELETE OLD!!!!!!

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COOLA CLASSIC FACE SUNSCREEN CUCUMBER BROAD SPECTRUM SPF 30
 avobenzon homosalate octisalate octocrylene lotion

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:79753-073 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------------------------------------------------------------|--------------------------|------------------|
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 1.75 g in 100 mL |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 2.5 g in 100 mL |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 1.5 g in 100 mL |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 3.75 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| AMYRIS BALSAMIFERA OIL (UNII: I1BJ961J2E) | |
| BRASSICA RAPA SUBSP. OLEIFERA OIL (UNII: N4G8379626) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| CAMELINA SATIVA SEED OIL (UNII: 12824X01L0) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| CARTHAMUS TINCTORIUS SEED OLEOSOMES (UNII: 9S60Q72309) | |
| SAFFLOWER OIL (UNII: 65UEH262IS) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| CETYL PALMITATE (UNII: 5ZA2S6B08X) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| CITRONELLYL ACETATE (UNII: IZ420RT3OY) | |
| ORANGE OIL (UNII: AKN3KSD11B) | |
| DECANAL (UNII: 31Z90Q7KQJ) | |
| DECYL GLUCOSIDE (UNII: Z17H97EA6Y) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| 2,6-DIMETHYL-5-HEPTENAL (UNII: Z331YX9EL9) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| 1,2-HEXANEDIOL (UNII: TR046Y3K1G) | |
| 3-HEXEN-1-OL, (3Z)- (UNII: V14F8G75P4) | |
| HEXENYL ACETATE, (2Z)- (UNII: PT792BQ57D) | |
| HEXYL ACETATE (UNII: 7U7KU3MWT0) | |
| HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W) | |
| JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL) | |
| MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y) | |
| LINALYL ACETATE (UNII: 5K47SSQ51G) | |
| MAURITIA FLEXUOSA FRUIT OIL (UNII: 48H19MS04L) | |
| METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F) | |
| NEROL (UNII: 38G5P53250) | |
| OPUNTIA FICUS-INDICA WHOLE (UNII: 23Z87HTQ6P) | |
| AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9) | |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) | |
| RASPBERRY SEED OIL (UNII: 9S8867952A) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| DISODIUM PHTHALATE (UNII: QB14YV193C) | |
| SORBITAN MONOOLEATE (UNII: 06XEA2VD56) | |
| SORBITAN MONOPALMITATE (UNII: 77K6Z421KU) | |
| SQUALANE (UNII: GW89575KF9) | |

| | |
|--------------------------------------------|--|
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | |
| TROPOLONE (UNII: 7L6DL16P1T) | |
| WATER (UNII: 059QF0KO0R) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

| Packaging | | | | |
|------------------|------------------|----------------------------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:79753-073-02 | 1 in 1 CARTON | 02/01/2023 | |
| 1 | | 25 mL 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 | 02/01/2023 | |

Labeler - COOLA LLC (956990290)

Revised: 4/2023

COOLA LLC