

BODY DEFENCE SUNSCREEN BROAD SPECTRUM SPF30- octinoxate, octisalate, homosalate, avobenzone, and octocrylene oil
ZELENS Limited

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.

BODY DEFENCE SUNSCREEN Broad Spectrum SPF30

Drug Facts

| Active ingredients | Purpose |
|---------------------------|----------------|
| Avobenzone 3.0% | Sunscreen |
| Homosalate 5.0% | Sunscreen |
| Octinoxate 7.5% | Sunscreen |
| Octisalate 5.0% | Sunscreen |
| Octocrylene 2.75% | 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 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

- 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 other 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

Other information

- protect this product from excessive heat and direct sun

- you may report a serious adverse reaction to this product to: Report Reaction, LLC
PO Box 22 Plainsboro, NJ 08536-0222

Inactive ingredients

Caprylic/Capric Triglyceride, Neopentyl Glycol Diheptanoate, Butyloctyl Salicylate, Dicaprylyl Ether, Olea Europaea (Olive) Fruit Oil, Sesamum Indicum (Sesame) Seed Oil, Vitis Vinifera (Grape) Seed Oil, Polyester-7, Phospholipids, Perilla Frutescens Leaf Extract, Astragalus Membranaceus Root Extract, Curcuma Longa (Turmeric) Root Extract, Camellia Sinensis Leaf Extract, Centella Asiatica Extract, Emblica Officinalis Fruit Extract, Echinacea Angustifolia Leaf Extract, Polypodium Leucotomos Root Extract, Rhodiola Rosea Root Extract, Silybum Marianum Extract, Ginkgo Biloba Leaf Extract, Pinus Strobus Bark Extract, Daucus Carota Sativa (Carrot) Root Extract, Glycine Soja (Soybean) Sterols, Glycolipids, Glycine Soja (Soybean) Oil, Zingiber Officinale Root Oil, Citrus Bergamia Melarosa Peel Oil Expressed, Citrus Limon Peel Oil, Citrus Aurantium Leaf Oil, Citrus Aurantifolia Peel Oil Distilled, Juniperus Mexicana Wood Oil, Coriandrum Sativum Seed Oil, Elettaria Cardamomum Seed Oil, Ferula Kokanica Resin Oil, Litsea Cubeba Fruit Oil, Myristica Fragrans Fruit Oil (Nutmeg), Salvia Sclarea Flower Oil, Thymus Vulgaris Oil, Tocopherol.

PRINCIPAL DISPLAY PANEL - 125 mL Bottle Box

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Body Defence

SUNSCREEN

BROAD SPECTRUM SPF 30

Water Resistant (40 minutes)

Silky Oil

125 mL / 4.2 Fl. Oz.



Drug Facts (continued)

Inactive ingredients (continued)

Emblica Officinalis Fruit Extract, Echinacea Angustifolia Leaf Extract, Polypodium Leucotomos Root Extract, Rhodiola Rosea Root Extract, Silybum Marianum Extract, Ginkgo Biloba Leaf Extract, Pinus Strobus Bark Extract, Daucus Carota Sativa (Carrot) Root Extract, Glycine Soja (Soybean) Sterols, Glycolipids, Glycine Soja (Soybean) Oil, Zingiber Officinale Root Oil, Citrus Bergamia Melarosa Peel Oil Expressed, Citrus Limon Peel Oil, Citrus Aurantium Leaf Oil, Citrus Aurantifolia Peel Oil Distilled, Juniperus Mexicana Wood Oil, Coriandrum Sativum Seed Oil, Elettaria Cardamomum Seed Oil, Ferula Kokanica Resin Oil, Litsea Cubeba Fruit Oil, Myristica Fragrans Fruit Oil (Nutmeg), Salvia Sclarea Flower Oil, Thymus Vulgaris Oil, Tocopherol.

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Body Defence

SUNSCREEN
BROAD SPECTRUM SPF 30
Water Resistant (40 minutes)

Silky Oil



152 Grosvenor Road
London SW1V 3JL, UK
www.zelens.com



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The ultimate, silky-touch sunscreen oil formulated using superior micro-encapsulation technology to provide broad-spectrum UVA/UVB protection (SPF 30). Enriched with powerful antioxidants, this advanced sun-defying formula reduces free radical formation and helps prevent sun damage. Replenishes moisture, reinforces the skin's natural barrier and combats signs of premature skin aging. Leaves skin feeling smooth, supple and protected.

May be used on the hair.
Water-resistant (40 minutes).
Dermatologist tested.

warnings

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CONTINUE ➔

BODY DEFENCE SUNSCREEN BROAD SPECTRUM SPF30

octinoxate, octisalate, homosalate, avobenzone, and octocrylene oil

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63712-201

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 75 mg in 1 mL |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 50 mg in 1 mL |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 50 mg in 1 mL |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 30 mg in 1 mL |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 27.5 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X) | |
| BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3) | |
| DICAPRYLYL ETHER (UNII: 77JZM5516Z) | |
| OLIVE OIL (UNII: 6UYK2W1W1E) | |
| SESAME OIL (UNII: QX10HYY4QV) | |
| GRAPE SEED OIL (UNII: 930MLC8XGG) | |
| POLYESTER-7 (UNII: 0841698D2F) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |
| PERILLA FRUTESCENS LEAF (UNII: T4L5881Y68) | |
| ASTRAGALUS PROPINQUUS ROOT (UNII: 922OP8YUPF) | |
| TURMERIC (UNII: 856YO1Z64F) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| CENTELLA ASIATICA (UNII: 7M867G6T1U) | |
| ECHINACEA ANGUSTIFOLIA LEAF (UNII: FS7G8S6PJ8) | |
| GINKGO (UNII: 19FUJ2C58T) | |
| PINUS STROBUS BARK (UNII: 8PJ4761097) | |
| PHYLLANTHUS EMBLICA FRUIT (UNII: YLX4CW2576) | |
| PHLEBODIUM AUREUM ROOT (UNII: VPS45WB8U) | |
| SEDUM ROSEUM ROOT (UNII: 3S5ITS5ULN) | |
| MILK THISTLE (UNII: U946SH95EE) | |
| CARROT (UNII: L56Z1JK48B) | |
| SOY STEROL (UNII: PL360EPO9J) | |
| SOYBEAN OIL (UNII: 241ATL177A) | |
| GINGER (UNII: C5529G5JPQ) | |
| BERGAMOT OIL (UNII: 39W1PKE3J) | |
| LEMON OIL (UNII: I9GRO824LL) | |
| BITTER ORANGE OIL (UNII: 9TLV70SV6I) | |
| LIME OIL (UNII: UZH29XGA8G) | |
| CEDRUS ATLANTICA BARK OIL (UNII: ZX5QRE4U60) | |
| CORIANDER OIL (UNII: 7626GC95E5) | |
| CARDAMOM OIL (UNII: JM0KJ091HZ) | |
| GALBANUM OIL (UNII: 211UF7M8N1) | |
| LITSEA OIL (UNII: 2XIW34BN6O) | |
| NUTMEG OIL (UNII: Z1CLM48948) | |
| CLARY SAGE OIL (UNII: 87L0D4U3M0) | |

| | |
|--------------------------------------|--|
| THYME OIL (UNII: 2UK410MY6B) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|--|
| Color | yellow | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:63712-201-01 | 1 in 1 BOX | 05/01/2016 | |
| 1 | | 125 mL in 1 BOTTLE, PUMP; 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 | 05/01/2016 | |

Labeler - ZELENIS Limited (217149018)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| Orignitalia | | 441072253 | manufacture(63712-201) |

Revised: 11/2019

ZELENIS Limited