

PROTECT AND PRIME BROAD SPECTRUM SPF30- avobenzone, octinoxate, octocrylene, oxybenzone cream
Emma Hardie Ltd

Protect & Prime Broad Spectrum SPF30

Drug Facts

Active ingredients

Avobenzone 3%

Octinoxate 7.5%

Octocrylene 10%

Oxybenzone 6%

Purpose

Sunscreen

Use

- Helps prevent sunburn

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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply generously 15 minutes before sun exposure
- Use a Water Resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours

- 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: **Sun Protection Measures.**
- Limit time in the sun, especially from 10 a.m. - 2 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses



Other information

- Protect the product in this container from excessive heat and direct sun

Inactive ingredients

Water (Aqua), caprylic/capric triglyceride, Green Wattle (Acacia Decurrens)/Jojoba (Simmondsia Chinensis)/Sunflower (Helianthis Annus) Seed Wax/Polyglyceryl-3 Esters, HDI/Trimethylol Hexyllactone Crosspolymer, Tapioca Starch, Manketti (Schinziophyton Rautaneii) Kernel Oil, Shea Butter (Vitellaria Paradoxa), Stearic Acid, Glycerin, Butylene Glycol Stearate SE, Phenoxyethanol, Benzyl Alcohol, Sodium Stearoyl Glutamate, Tocopheryl Acetate, Fragrance (Parfum), Polyhydroxystearic Acid, Geraniol, Limonene, Citronellol, Xanthan Gum, Linalool, Alumina, Aluminum Stearate, Disodium EDTA, Ethylhexylglycerin, Dehydroacetic Acid, Silica, Sodium Stearate, Polymethylsilsesquioxane, Disodium Rutinyl Disulfate, Barley (Hordeum Districhon) Extract, Lemon Balm (Melissa Officinalis) Leaf Extract, Sodium Benzoate, Citral, Citric Acid, Farnesol, Titanium Dioxide (CI 77891)

Package Labling:

| <p><i>Look Younger, Naturally</i></p> <p>EMMA HARDIE SKINCARE <i>Emma Hardie Skincare is based on targeted botanicals to support complexions of all ages and skin concerns to help the skin look younger naturally.</i></p> <p>FORMULATED WITHOUT</p> <ul style="list-style-type: none"> • Synthetic colours • Synthetic fragrance • Petrolatum • Mineral oil • Animal ingredients  <p>MADE IN BRITAIN</p> |  <p>PROTECT & PRIME SPF 30</p> <ul style="list-style-type: none"> • A lightweight, hydrating and protecting daily moisturiser. • Smooths and primes the skin for a soft focus, luminous finish. • Provides UVA and UVB SPF 30 protection. <p>30 ml e 1.7 fl.oz.</p> | <p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Azobenzene 3% Octinoxate 7.5% Oxybenzone 10% Oxybenzone 6%</td> <td>Sunscreen</td> </tr> </tbody> </table> <p>Use</p> <ul style="list-style-type: none"> • Helps prevent sunburn <p>Warnings</p> <p>For external use only</p> <p>Do not use on damaged or broken skin</p> <p>When using this product keep out of eyes. Rinse with water to remove.</p> <p>Stop use and ask a doctor if rash occurs</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> • Apply generously 15 minutes before sun exposure • Use a Water Resistant sunscreen if swimming or sweating • Reapply 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: <ul style="list-style-type: none"> • Limit time in the sun, especially from 10 a.m. - 2 p.m. • Wear long-sleeved shirts, pants, hats, and sunglasses <p>Other information • Protect the product in this container from excessive heat and direct sun</p> <p>Inactive ingredients Aqua (Water), Caprylic/Capric Triglyceride, Butyl, Jojoba Esters, Titanium Dioxide, Hexylmethylsil-Hexylolactone Crosspolymer, Tapioca Starch, Helianthus Annuus (Sunflower) Seed Wax, Butylene Glycol, Butyrospermum Parkii (Shea) Butter, Glycerin, Glyceryl Stearate SE, Schinziophyton Rautaneii Kernel Oil, Stearic Acid, Phenoxyethanol, Benzyl Alcohol, Sodium Stearoyl Glutamate, Tocopheryl Acetate, Parfum (Fragrance), Polyhydroxystearic Acid, Geraniol, Limonene, Citronellol, Xanthan Gum, Linalool, Alumina, Aluminum Stearate, Acacia Decurrens Flower Extract, Polyglycerol-3, Disodium EDTA, Ethylhexylglycerin, Dihydroacetic Acid, Silica, Polymethylsilsesquioxane, Hordeum Vulgare (Barley), Hordeum Distichon (Barley) Extract, Melissa Officinalis Leaf Extract, Sodium Benzoate, Citral, Citric Acid, Farnesol.</p> <p>To report a serious adverse event contact NCC Consultancy at 917-917-8584</p> | Active ingredients | Purpose | Azobenzene 3% Octinoxate 7.5% Oxybenzone 10% Oxybenzone 6% | Sunscreen | <p>PROTECT & PRIME SPF 30</p> <p>A lightweight, non-greasy skin protecting and priming cream with a broad-spectrum SPF30, giving daily protection against UVA and UVB damage. Specially formulated with Mongongo Oil, Barley Extract and Vitamin E to help protect and guard the skin from signs of premature ageing, sun and environmental damage. It also contains a unique light diffusing ingredient to help prime the skin, even out the complexion and blur the appearance of fine lines and pores.</p> <p>MADE IN ENGLAND FOR EMMA HARDIE LTD.</p> <p>Emma Hardie Ltd. NW1 1AD, U.K., Tel: +44 (0) 20 3874 3040 www.emmahardie.com</p> <p>Emma Hardie is a registered trademark of Emma Hardie Ltd.</p> |
|--|--|---|--------------------|---------|---|-----------|--|
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To report a serious adverse event contact KCC Consultancy at 917-817-2524

PROTECT AND PRIME BROAD SPECTRUM SPF30

avobenzone, octinoxate, octocrylene, oxybenzone cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70453-001 |
| 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 |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 75 mg in 1 mL |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 100 mg in 1 mL |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE | 60 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| SIMMONDSIA CHINENSIS SEED WAX (UNII: 47X6Y9FJJ2) | |
| HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV) | |
| HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9) | |
| SCHINZIOPHYTON RAUTANENII SEED OIL (UNII: 6GSJ7A6T1E) | |
| SHEA BUTTER (UNII: K49155WL9Y) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| 1,4-BUTANEDIOL MONOSTEARATE (UNII: OY671H06VI) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| GERANIOL (UNII: L837108USY) | |
| .BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| LINALOOL, (+/-)- (UNII: D81QY6I88E) | |
| ALUMINUM OXIDE (UNII: LMI26O6933) | |
| ALUMINUM STEARATE (UNII: U6XF9NP8HM) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| DEHYDROACETIC ACID (UNII: 2KAG279R6R) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| SODIUM STEARATE (UNII: QU7E2XA9TG) | |
| DISODIUM RUTINYL DISULFATE (UNII: V5J3537PND) | |
| BARLEY (UNII: 5PWM7YLI7R) | |
| MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| CITRAL (UNII: T7EU009VPP) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| FARNESOL (UNII: EB41QIU6JL) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70453-001-01 | 1 in 1 BOX | 02/03/2016 | |
| - | | 50 mL in 1 BOTTLE; Type 0: Not a Combination | | |

| Product | | | |
|------------------------------|--|----------------------|--------------------|
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M020 | 02/03/2016 | |

Labeler - Emma Hardie Ltd (346913440)

Revised: 11/2023

Emma Hardie Ltd