SKIN LONG-WEAR WEIGHTLESS FOUNDATION BROAD SPECTRUM SPF 15octinoxate and titanium dioxide lotion Bobbi Brown Professional Cosmetics 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.

SKIN LONG-WEAR WEIGHTLESS FOUNDATION BROAD SPECTRUM SPF 15 Drug Facts

Active Ingredients

Octinoxate 3.0%
Titanium Dioxide 1.6%

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

Directions

For suncreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every two 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 suncreen 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

Inactive ingredients

water\aqua\eau • dimethicone • trimethylsiloxysilicate • cetyl peg/ppg-10/1 dimethicone • butylene glycol • glycerin • disteardimonium hectorite • polyglyceryl-3 diisostearate • sodium chloride • laminaria saccharina extract • butyrospermum parkii (shea butter) • fragrance (parfum) • ascorbyl palmitate • tocopherol • dimethicone crosspolymer • methicone • stearic acid • tocopheryl acetate • glyceryl oleate • lecithin • glyceryl stearate • citric acid • aluminum hydroxide • talc • disodium edta • linalool • sodium dehydroacetate • phenoxyethanol • [+/- mica • titanium dioxide (ci 77891) • iron oxides (ci 77492) • iron oxides (ci 77491) • iron oxides (ci 77499)] <iln44078>

Other information

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

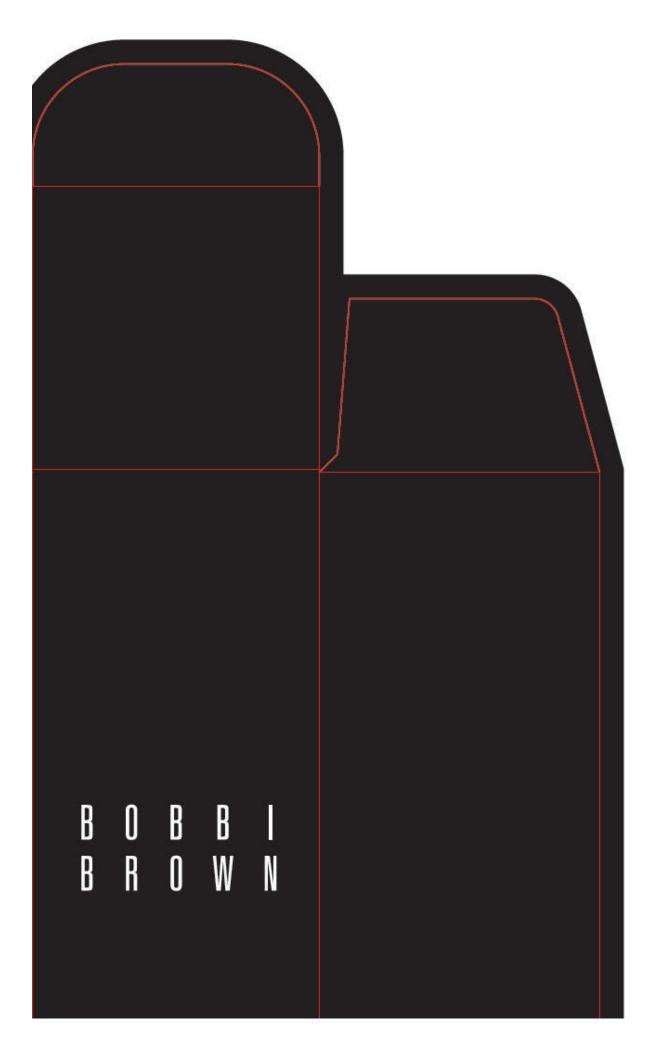
PRINCIPAL DISPLAY PANEL - 30 ml Bottle Carton

BOBBI BROWN

Skin Long-Wear Weightless Foundation Broad Spectrum SPF 15

Full Cover
Oil-Free Shine Control

1 FL. OZ./30 ml e





C165080

Skin Long-Wear Weightless Foundation Broad Spectrum SPF 15

Full, long-wear coverage that looks and feels like skin—not masky, heavy or cakey. This high-performance, oil-free formula creates a poreless, shine-free finish with incredibly comfortable day-to-night wear.

- Silky emulsion of true-to-skin pigments, hydrating emollients and wear-extending ingredients floats over skin and delivers flexible, breathable coverage.
- Instantly mattifies oily skin for a natural look that is never dry, dull or flat. It helps minimize oil throughout the day, and reduces the appearance of pores over time.
- Stays fresh all day—and into the night—with coverage that lasts even in hot and humid climates.

Usage: Prime skin with moisturizer, then apply foundation with brush, sponge or fingers. Shake well before use.

© Dist. Bobbi Brown Professional Cosmetics N.Y., N.Y. 10022 • <u>WLB LTD, GU32 3DD, UK</u> New York • London • Paris Made in Belgium [EGXR] **WWW.BOBBIBROWN.COM**





FPO/UPC 1-5/16 x 17/32 neips prevent sundum

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

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every two 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

Inactive ingredients

water\aqua\eau • dimethicone • trimethylsiloxysilicate • cetyl peg/ppg-10/1 dimethicone • butylene glycol • glycerin • disteardimonium hectorite • polyglyceryl-3 diisostearate • sodium chloride • laminaria saccharina extract • butyrospermum parkii (shea butter) • fragrance (parfum) • ascorbyl palmitate • tocopherol • dimethicone crosspolymer • methicone • stearic acid • tocopheryl acetate • glyceryl oleate • lecithin • glyceryl stearate • citric acid • aluminum hydroxide • talc • disodium edta • linalool • sodium dehydroacetate • phenoxyethanol • [+/- mica • titanium dioxide (ci 77891) • iron oxides (ci 77492) • iron oxides (ci 77491) • iron oxides (ci 77499)] <iln44078>

Other information

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

EGXR-01-1111



SKIN LONG-WEAR WEIGHTLESS FOUNDATION BROAD SPECTRUM SPF 15

octinoxate and titanium dioxide lotion

| Product Information | | | |
|----------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:64141-025 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | | | |
|--|--------------------------|---------------|--|--|--|
| Ingredient Name | Basis of Strength | Strength | | | |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 30 mg in 1 mL | | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 16 mg in 1 mL | | | |

| Inactive Ingredients | |
|--|----------|
| Ingredient Name | Strength |
| WATER (UNII: 059QF0KO0R) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L) | |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SACCHARINA LATISSIMA (UNII: 68CMP2MB55) | |
| SHEA BUTTER (UNII: K49155WL9Y) | |
| ASCORBYL PALMITATE (UNII: QN83US2B0N) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6) | |
| METHICONE (20 CST) (UNII: 6777U11MKT) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| .ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| GLYCERYL OLEATE (UNII: 4PC054V79P) | |
| GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) | |
| TALC (UNII: 7SEV7J4R1U) | |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) | |

LINALOOL, (+/-)- (UNII: D81QY6I88E)

SODIUM DEHYDROACETATE (UNII: 8W46YN971G)

PHENOXYETHANOL (UNII: HIE492ZZ3T)

MICA (UNII: V8A1AW0880)

FERRIC OXIDE YELLOW (UNII: EX43802MRT)

FERRIC OXIDE RED (UNII: 1K09F3G675)

FERROSOFERRIC OXIDE (UNII: XM0M87F357)

| P | Packaging | | | | | | |
|---|----------------------|--|-------------------------|-----------------------|--|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | | |
| 1 | NDC:64141-025- 01 | 1 in 1 CARTON | 07/21/2017 | | | | |
| 1 | | 30 mL in 1 BOTTLE; Type 0: Not a Combination Product | | | | | |
| 2 | NDC:64141-025- 02 | 1 in 1 CARTON | 12/22/2022 | | | | |
| 2 | | 13 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 final | M020 | 07/21/2017 | | | |
| | | | | | |

Labeler - Bobbi Brown Professional Cosmetics Inc. (627131279)

Registrant - Estee Lauder Companies Inc. (790802086)

| Establishment | | | | | |
|---------------|---------|-----------|-----------------------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| PALC | | 078364654 | pack(64141-025), label(64141-025) | | |

| Establishment | | | |
|-----------------------------|---------|-----------|------------------------------------|
| Name | Address | ID/FEI | Business Operations |
| Estee Lauder Cosmetics Ltd. | | 204132062 | pack(64141-025) , label(64141-025) |

| Establishment | | | |
|---------------------------|---------|-----------|---|
| Name | Address | ID/FEI | Business Operations |
| Whitman Laboratories Ltd. | | 216866277 | manufacture(64141-025) . pack(64141-025) . label(64141-025) |

| Establishment | | | | | |
|-------------------|---------|-----------|---|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| Estee Lauder N.V. | | 370151326 | manufacture(64141-025) , pack(64141-025) , label(64141-025) | | |

| Establishment | | | | | |
|----------------------|---------|-----------|---|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| The Estee Lauder Inc | | 802599436 | manufacture(64141-025), pack(64141-025), label(64141-025) | | |

| Establishment | | | | | |
|---------------|---------|-----------|------------------------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| Northtec LLC | | 943871157 | pack(64141-025) , label(64141-025) | | |

| Establishment | | | | | |
|---------------|---------|-----------|------------------------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| PADC 1 | | 949264774 | pack(64141-025) , label(64141-025) | | |

Revised: 1/2023 Bobbi Brown Professional Cosmetics Inc.