

**LEG BODY MAKEUP- octisalate, octocrylene cream  
COSMAX USA, CORPORATION**

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**DERMABLEND Leg and Body Makeup SPF25- LIGHT NATURAL**

***Active Ingredients***

Octisalate 3.2%

Octocrylene 6.2%

***Purpose***

Sunscreen

**USES**

***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 cause by the sun

**Warnings**

***Warnings***

**For extenal 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**

***Directions***

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- 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. - 2p.m.
    - wear long-sleeved shirts, pants, hats and sunglasses

- children under 6 months of age: Ask a doctor

## **OTHER INFORMATION**

### ***Other information***

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

***Inactive ingredients*** Water, Cyclopentasiloxane, Isododecane, Isononyl Isononanoate, Glycerin, Cetyl PEF/PPG-10/1 Dimethicone, Dimethicone, Magnesium Sulfate, Polyglyceryl-4 Isostearate, Dimethicone/PEG-10/15 Crosspolymer, Disodium Stearoyl Glutamate, Distearidimonium Hectorite, Phenoxyethanol, Polybutene, Methylparaben, Alcohol Denat, Chlorphenesin, Acrylonitrile/methyl methacrylate/vinylidene chloride, Copolymer, Butylparaben, Aluminum Hydroxide, Sodium Hyaluronate, Isobutane, Dipropylene Glycol, Sodium Citrate, Tocopherol, Pentaerythrityl tetra-di-butyl hydroxyhydrocinnamate; may contain, Titanium Dioxide, Iron Oxides.

## **QUESTIONS or COMMENTS**

### ***Questions or comments?***

1-8771-877-900-6700 Monday - Friday (9 a.m. - 5 p.m. EST)

Primary Package (Inner)

## Tube Dimensions Decoration Area

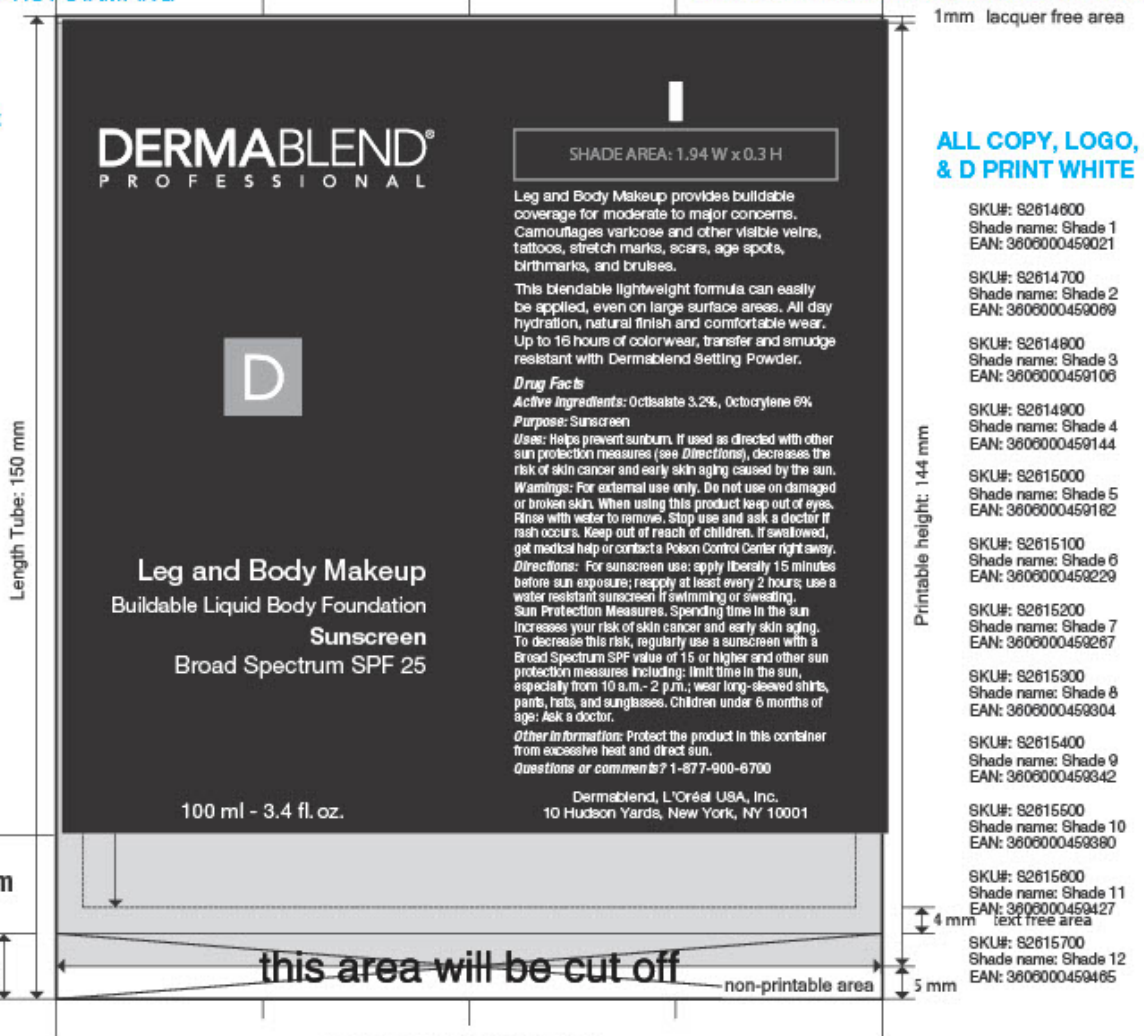
|                    |                              |                                   |             |
|--------------------|------------------------------|-----------------------------------|-------------|
| <b>Summary:</b>    |                              | <b>Dieline number</b>             | <b>3084</b> |
| Date:              | 27.05.2016                   | Total height incl. shoulder       | ,0 mm       |
| Project:           | Dermablend                   | Cap height                        | ,0 mm       |
| Diameter x Length: | 40,0 mm x 150,0 mm           | <b>Eyemark position and size:</b> |             |
| Decoration:        | Silkscreen printing          | Width:                            | 2,0 mm      |
| Customer:          | L'Oreal USA                  | Height:                           | 6,0 mm      |
| Creator:           | Lingfeld                     | Distance from top:                | 10,0 mm     |
| Line Thickness:    | pos & neg (rev. out) 0.15 mm | Distance to Print Text:           | 1,0 mm      |

FOIL STAMP  
NOTE: KNOCK-OUT WHITE SQUARE ON BLACK BACKGROUND PRIOR TO STAMPING "D" KNOCKS OUT OF HOT STAMPING

OPEN END OF THE TUBE  
distance between center marks 63 mm

ALL TYPE ON BACK PANEL IS 6.5 PT,  
EXCEPT THE WORDS "DRUG FACTS" 7pt  
NO MORE THAN 33 CHARACTERS/INCH

FRONT PANEL:  
Product Form: 12pt  
Descriptor: 9pt  
Sunscreen: 10pt  
Weight: 9pt



ALL COPY, LOGO,  
& D PRINT WHITE

- SKU#: 82614800  
Shade name: Shade 1  
EAN: 3606000459021
- SKU#: 82614700  
Shade name: Shade 2  
EAN: 3606000459069
- SKU#: 82614800  
Shade name: Shade 3  
EAN: 3606000459106
- SKU#: 82614900  
Shade name: Shade 4  
EAN: 3606000459144
- SKU#: 82615000  
Shade name: Shade 5  
EAN: 3606000459182
- SKU#: 82615100  
Shade name: Shade 6  
EAN: 3606000459229
- SKU#: 82615200  
Shade name: Shade 7  
EAN: 3606000459267
- SKU#: 82615300  
Shade name: Shade 8  
EAN: 3606000459304
- SKU#: 82615400  
Shade name: Shade 9  
EAN: 3606000459342
- SKU#: 82615500  
Shade name: Shade 10  
EAN: 3606000459380
- SKU#: 82615600  
Shade name: Shade 11  
EAN: 3606000459427
- SKU#: 82615700  
Shade name: Shade 12  
EAN: 3606000459465

Circumference/Unrolling: 126 mm

### TUBE HEAD

NOTE:  
BACK ALL ART IN WHITE

|  |   |  |
|--|---|--|
| <b>DERMABLEND</b><br>PROFESSIONAL      |   | OFFSET / FLEXO / SCREEN / ETC.                       |
| DIVISION: ACTIVE COSMETICS             |   | <input type="checkbox"/> E-SCREEN/BLACK/BLACK/UV-360 |
| PRODUCT: LEG & BODY MAKEUP             |   | <input type="checkbox"/> WHITE SCREEN FOR COPY       |
| LABEL CLAIM: 100 mL - 3.4 fl oz        | COMPONENT DESC: TUBE                              |  |
| DATE CREATED: 4/22/18                  | RELEASE DATE(s): TBD                              |  |
| SOFTWARE: ILLUSTRATOR CC               | FILE NAME: Derm.MF4 LB BSHO TREATWORK_30MM1213184 |  |
| FONTS: CONVERTED TO OUTLINE            |   | HOT STAMP:   |
| REVISION HISTORY: NEW DIELINE          |   | <input type="checkbox"/> BRIGHT SILVER 85-04100      |
| COMPONENT NO.: 380806 2133884 - 8PF 26 |   | EMBOSSING:   |
| *DECO COMP. NO.: N/A                   | See upper in 433 folder<br>(360 000 000 459 381)  | <input type="checkbox"/>                             |
| FG. NO.: SEE SIDE                      | DWG. NO.: 2888                                    | NON PRINTING:  |
| UPC / EAN NO.: TBD                     |   | <input checked="" type="checkbox"/> DIELINE          |
| LANGUAGE SET: ENGLISH                  |   | <input type="checkbox"/>                             |
|  |   | <input type="checkbox"/>                             |
|  |   | <input type="checkbox"/>                             |



shade Label



## LEG BODY MAKEUP

octisalate, octocrylene cream

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:68577-111 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength         |
|---|-------------------|------------------|
| <b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE       | 6 mg in 100 mg   |
| <b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)   | OCTISALATE        | 3.2 mg in 100 mg |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)  |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)  |          |
| <b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)  |          |
| <b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)  |          |
| <b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)  |          |
| <b>ISOBUTANE</b> (UNII: BXR49TP611)   |          |
| <b>DIMETHICONE/PEG-10/15 CROSSPOLYMER</b> (UNII: 21AS8B1BSS)  |          |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)  |          |
| <b>ISONONYL ISONONANOATE</b> (UNII: S4V5BS6GCX)   |          |
| <b>ISODODECANE</b> (UNII: A8289P68Y2)   |          |
| <b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5)</b> (UNII: V2W71V8T0X)                                  |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)  |          |
| <b>FERROUS OXIDE</b> (UNII: G7036X8B5H)   |          |
| <b>WATER</b> (UNII: 059QF0KO0R)   |          |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)   |          |
| <b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)   |          |
| <b>BUTYLPARABEN</b> (UNII: 3QPI1U3FV8)  |          |
| <b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)  |          |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)  |          |
| <b>PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE)</b> (UNII: 255PIF62MS) |          |
| <b>ALCOHOL</b> (UNII: 3K9958V90M)   |          |
| <b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)  |          |
| <b>MAGNESIUM SULFATE, UNSPECIFIED FORM</b> (UNII: DE08037SAB)                                       |          |
| <b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)   |          |
| <b>DISODIUM STEAROYL GLUTAMATE</b> (UNII: 45ASM2L11M)   |          |
| <b>POLYBUTENE (1400 MW)</b> (UNII: 1NA5AO9GH7)  |          |

**CHLORPHENESIN** (UNII: I670DAL4SZ)

**GLATIRAMER ACETATE** (UNII: 5M691HL4BO)

### Packaging

| # | Item Code        | Package Description                                 | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:68577-111-01 | 1 in 1 CARTON                                       | 06/01/2023           |                    |
| 1 |                  | 100 mg 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 Drug | M020                                     | 06/01/2023           |                    |

**Labeler** - COSMAX USA, CORPORATION (010990210)

**Registrant** - COSMAX USA, CORPORATION (010990210)

### Establishment

| Name                    | Address | ID/FEI    | Business Operations    |
|-------------------------|---------|-----------|------------------------|
| COSMAX USA. CORPORATION |         | 010990210 | manufacture(68577-111) |

Revised: 12/2023

COSMAX USA, CORPORATION