

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

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

***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**

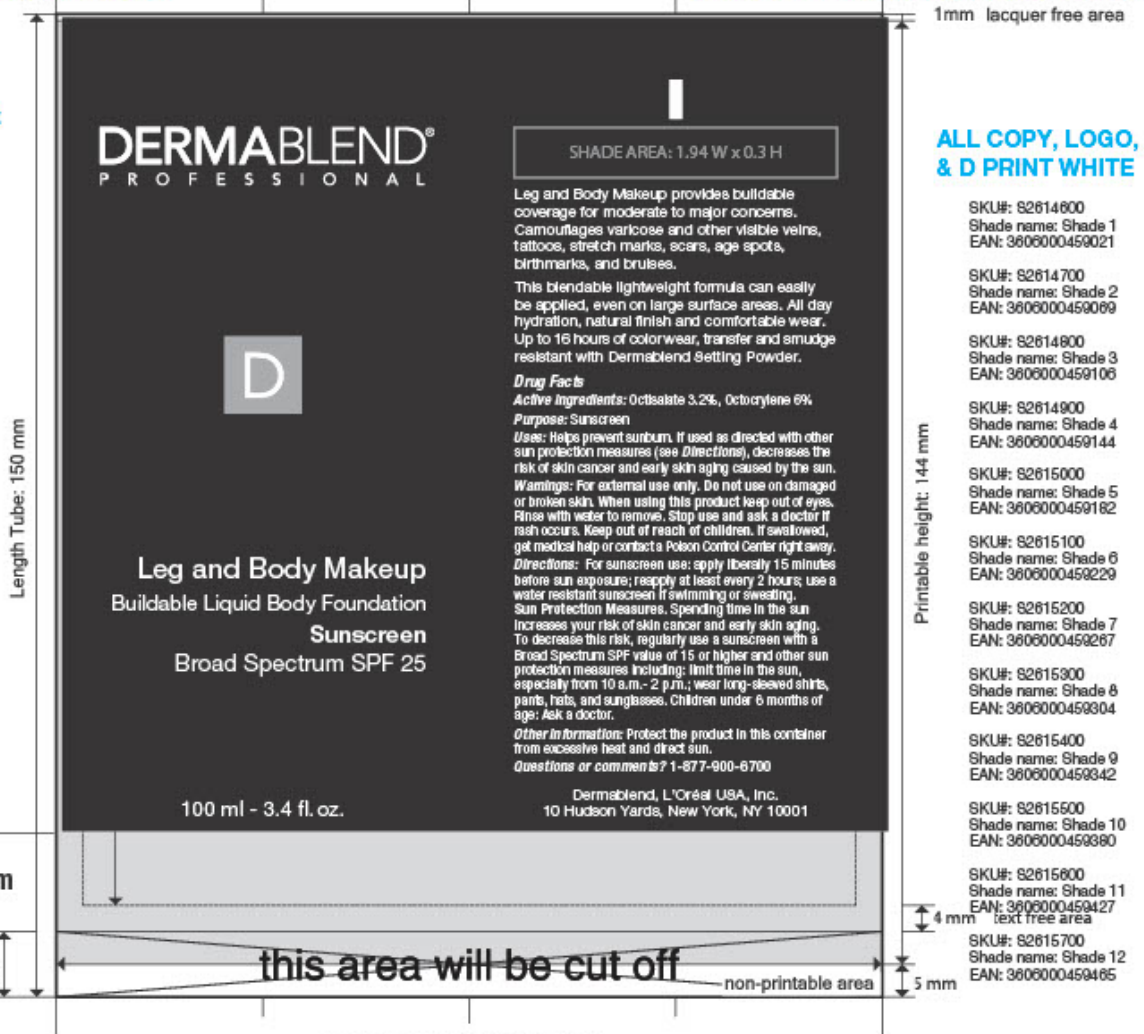
<b>Summary:</b>		<b>Dieline number</b>	<b>3084</b>
Date:	27.05.2016	Total height incl. shoulder	,0 mm
Project:	Dermablend	Cap height	,0 mm
Diameter x Length:	40,0 mm x 150,0 mm	<b>Eyemark position and size:</b>	
Decoration	Silkscreen printing	Width:	2,0 mm
Customer:	L'Oreal USA	Height:	6,0 mm
Creator:	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



<b>DERMABLEND</b> PROFESSIONAL		OFFSET / FLEKO / SCREEN / ETC.
DIVISION: ACTIVE COSMETICS		<input type="checkbox"/> USE DIE/BLAO: BLQ/UA/SD
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.MFL LB BND TREATWORK_MM181118184	
FONTS: CONVERTED TO OUTLINE		HOT STAMP:
REVISION HISTORY: NEW DIELINE		<input type="checkbox"/> BRIGHT SILK 85-04100
COMPONENT NO.: 380806 2133884 - 8PF 26		EMBOSSING:
*DECO COMP. NO.: N/A		<input type="checkbox"/>
FG. NO.: SEE SIDE	DWG. NO.: 2888	NON PRINTING:
UPC / EAN NO.: TBD		<input type="checkbox"/> DIELINE
LANGUAGE SET: ENGLISH		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>

**NOTE:**  
BACK ALL ART IN WHITE



## Shade Label

**LEG BODY MAKEUP**

octisalate, octocrylene cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68577-117
<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:68577-117-01	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(68577-117)

Revised: 12/2023

COSMAX USA, CORPORATION