

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

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**DERMABLEND Leg and Body Makeup SPF25- FAIR NUDE**

***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 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**

***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**

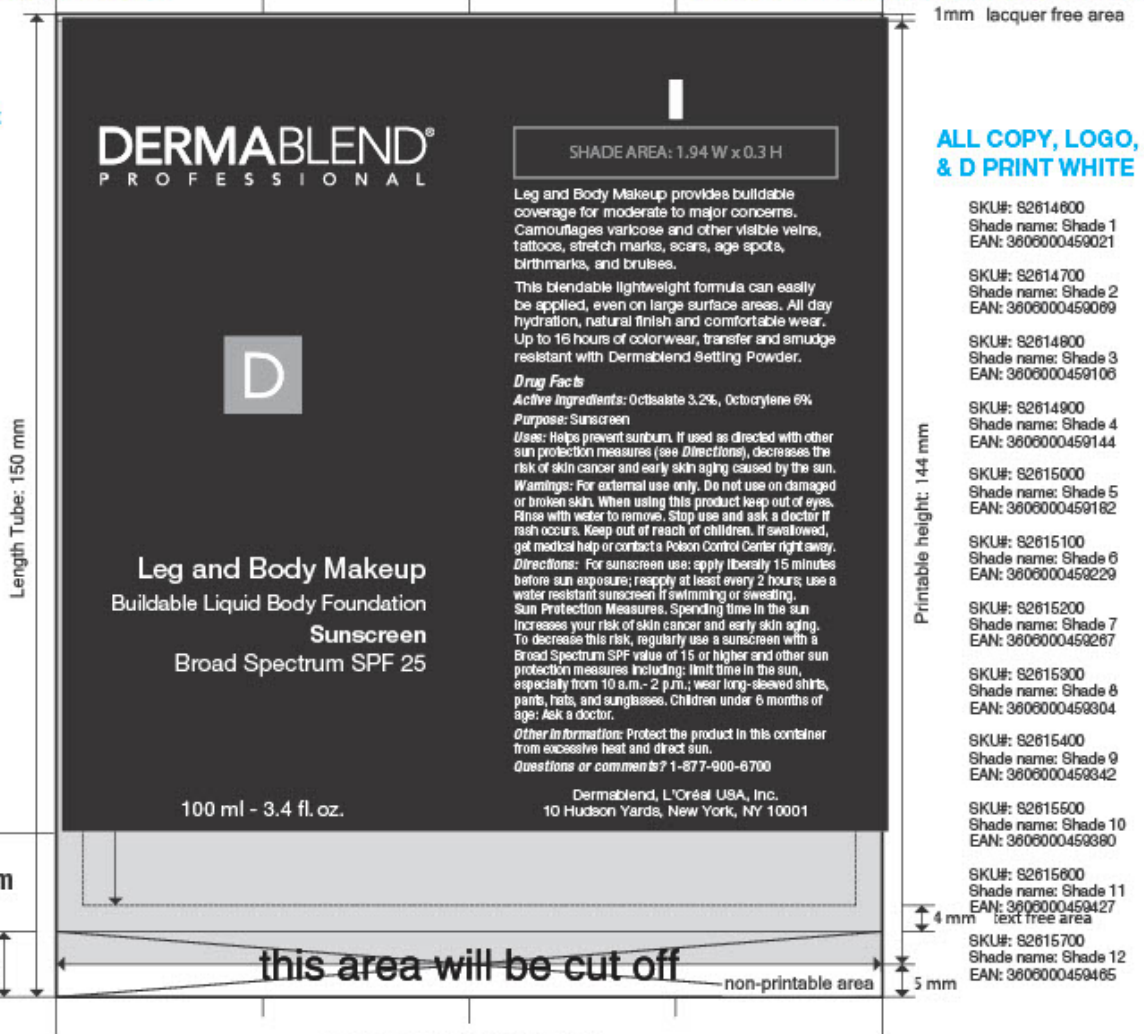
<b>Summary:</b>		<b>Dieline number</b>	<b>3084</b>
Date:	27.05.2016	Total height incl. shoulder	,0 mm
Project:	Dermablend	Cap height	,0 mm
Diameter x Length:	40,0 mm x 150,0 mm	<b>Eyemark position and size:</b>	
Decoration:	Silkscreen printing	Width:	2,0 mm
Customer:	L'Oreal USA	Height:	6,0 mm
Creator:	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		EMBOSSING
PRODUCT: LEG & BODY MAKEUP		NON PRINTING:
LABEL CLAIM: 100 mL - 3.4 fl oz	COMPONENT DESC: TUBE	DIENE
DATE CREATED: 4/22/18	RELEASE DATE(s): TBD	
SOFTWARE: ILLUSTRATOR CC	FILE NAME: Derm.MF4 LB BND TREATWORK_MMM1213184	
FONTS: CONVERTED TO OUTLINE		
REVISION HISTORY: NEW DIELINE		
COMPONENT NO.: 380806 2133884 - 8PF 26		
*DECO COMP. NO.: N/A		
FG. NO.: SEE SIDE	DWG. NO.: 2888	
UPC / EAN NO.: TBD		
LANGUAGE SET: ENGLISH		

**NOTE:**  
BACK ALL ART IN WHITE



<b>DIAMOND</b> packaging		111 Commerce Drive Rochester, NY 14623 Toll Free (800) 333-4079 (585) 334-8030 Fax (585) 334-9141			
Customer	L'oreal	File No.	L-2342	Item Desc.	360605 2133979
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
VARNISH	GLOSS COATING	BLACK 2 HITS	GREY 2 HITS	FOIL STAMP	
Checked By	Date	Q.A.	Date	X	Date

This proof is a representation of how the final printed product will appear. Special match colors have been simulated for this proof and may not view accurately. Please be sure to review thoroughly. Once approved, this proof will be referenced during production as an indication of our customer's requirements and expectations. Upon completion of your review, please indicate the following:

This Proof is:  OK to run - No Corrections  
 OK to run - With Corrections as indicated on the proof  
 NOT OK to run - Corrections indicated on the proof  
 Send revised proof for approval

Bleeds on the tucks and dust flaps may be altered to accommodate single knife layouts.  
 Please check here if you do not approve.

**YOUR SIGNATURE IS REQUIRED**

FCD-0020 Rev. 6

Outer Package (Secondary)

# LEG BODY MAKEUP

octisalate, octocrylene cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68577-110
<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)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>GLATIRAMER ACETATE</b> (UNII: 5M691HL4BO)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68577-110-01	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(68577-110)

Revised: 10/2023

COSMAX USA, CORPORATION