

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

DERMABLEND Leg and Body Makeup SPF25- MEDIUM GOLDEN

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)

Attention: No guarantee for accuracy within the dimensional sketch!



DIAMOND packaging		111 Commerce Drive Rochester, NY 14623 Toll Free (800) 333-4079 (585) 334-8030 Fax (585) 334-9141			
Customer	L'Oréal	File No.	L-2342	Item Desc.	360605 2133979
☐ 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)

Shade Label

MEDIUM GOLDEN 40W

*** Proofing Composite ***
Not all Varnishes and Whites
are shown in this preview.

Job Number - 983954		18-Nov-19	Lot 1	Rev 0
Part - 3606052160616		Description - DB LegBdyMdG 40W		
- Color Key -				
1 45° 31 40060 ULF DB MedGold 2 45° 31 Black 3 45° 31 _dieline_c				
- Materials -				
Base Stock - 13634 Higloss 60# S246		Substrate 2 - 10247 Clr Pp Gloss Lam		Substrate 3 --- Substrate 3 N/A --
Substrate 4 --- Substrate 4 N/A --		Coating 1 --- Coating N/A ---		Coating 2 --- Coating 2 N/A --
If this Epson hard proof was received, it will yield good color representation of four-color process on a Higloss paper with a UV coating. In all other scenarios, including those using spot colors, it is likely to yield accurate color. If this proof was received as a PDF, it will not be color accurate if viewed on a monitor or outputed on a customer's printer. Please notify your customer representative prior to proofing if there is a color standard to match. - Sign Approval -				
4 40060 ULF DB MedGold Pos. #4 "Narrow" Die-cut/Rolls - Operator - RR				
- Label Size - Around - 2.370 in Across - 1.300 in - Size of Internal Die Cuts - Around - N/A Across - N/A - Die Construction - Die No. - 10280 C. Radius - 0.015 in Space Ar. - 0.1300 in Space Ac. - 0.1250 in Step Ar. - 2.5000 in Step Ac. - 1.4250 in No. Ar. - 4 No. Ac. - 2 Plate Rpt. - 10.0000 in Plate Dist. - 96.10				

LEG BODY MAKEUP

octisalate, octocrylene cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68577-118
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)		OCTOCRYLENE	6 mg in 100 mg
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)		OCTISALATE	3.2 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ISOBUTANE (UNII: BXR49TP611)	
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
ISODODECANE (UNII: A8289P68Y2)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERROUS OXIDE (UNII: G7036X8B5H)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
ALCOHOL (UNII: 3K9958V90M)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)	
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
GLATIRAMER ACETATE (UNII: 5M691HL4BO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68577-118-01	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(68577-118)

Revised: 12/2024

COSMAX USA, CORPORATION