

**GARNIER OMBRELLE SPF 60 COMPLETE LIGHTWEIGHT- homosalate, octocrylene, octisalate, avobenzone, drometrizole trisiloxane and terephthalylidene dicamphor sulfonic acid lotion**  
**L'Oreal USA Products Inc**

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**Drug Facts**

**Active ingredients**

Homosalate 10%

Octocrylene 7%

Octisalate 5%

Avobenzone 4%

Drometrizole Trisiloxane 2.5%

Terephthalylidene Dicamphor Sulfonic Acid 0.5%

**Caution**

For external use only. Do not use on damaged or broken skin. If rash occurs, discontinue use and consult a health care practitioner. Keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed get medical help or contact a Poison Control Centre right away. Do not expose babies and young children directly to the sun. Avoid contact with textiles.

**Directions**

Apply generously and evenly 15 minutes before sun exposure. Reapply at least every 2 hours. Use a water resistant sunscreen if swimming or sweating. For use on children less than 6 months of age, consult a health care practitioner.

**Others**

Aqua, Glycerin, Alcohol Denat., Styrene/Acrylates Copolymer, Dimethicone, Propylene Glycol, PEG-100 Stearate, Glyceryl Stearate, Silica, Synthetic Wax, Phenoxyethanol, Sodium Polyacrylate, Triethanolamine, Stearic Acid, Caprylyl Glycol, Palmitic Acid, PEG-8 Laurate, Xanthan Gum, Tocopherol, Disodium EDTA

## TECHNOLOGIE

Le système filtrant breveté de Ombrelle®, avec la technologie Mexoryl® et autres filtres solaires, procure une protection UVA/UVB à large spectre efficace.

## BÉNÉFICES

- \*Ombrelle® FPS 60 Soins Complet est un soin hydratant complet pour le corps et le visage.
- Sa texture légère et non grasse s'absorbe rapidement et laisse la peau douce et confortable.
- Cette formule hypoallergénique ne contient ni parfum ni colorant.
- Cette lotion aide à prévenir les coups de soleil.

## MODE D'EMPLOI

Appliquer généreusement et uniformément 15 minutes avant l'exposition au soleil. Appliquer de nouveau au moins toutes les 2 heures. Utiliser un écran solaire résistant à l'eau lors d'une activité aquatique ou s'il y a transpiration. Pour les enfants âgés de moins de 6 mois, consulter un professionnel de la santé.

## MISE EN GARDE

Pour usage externe seulement. Ne pas utiliser sur une peau endommagée ou présentant des lésions. En présence d'une éruption cutanée, cesser l'utilisation et consulter un professionnel de la santé. Éviter tout contact avec les yeux. Rincer à l'eau le cas échéant. Garder hors de portée des enfants. En cas d'ingestion, consulter un médecin immédiatement ou appeler un centre antipoison. Ne pas exposer les bébés et les jeunes enfants directement au soleil. Éviter le contact avec les textiles.

## GARNIER®

Pionnier de la protection solaire depuis 1936.



www.ombrelle.ca  
1 888 9-OMBREL

Mexoryl® is a registered trademark / est une marque de commerce déposée de L'Oréal S.A. Imp. by / par Ombrelle Canada, Montreal H4T 1X5 2026530

## TECHNOLOGY

Ombrelle®'s patented filtering system with Mexoryl® technology and other sunscreen filters provides effective broad-spectrum UVA/UVB protection.

## BENEFITS

- \*Ombrelle® SPF 60 Complete is a complete moisturizing care for the body and face.
- Its light, non-greasy texture is quickly absorbed and will leave the skin soft and comfortable.
- This hypoallergenic formula is fragrance and colorant free.
- This lotion helps prevent sunburn.

## DIRECTIONS

Apply generously and evenly 15 minutes before sun exposure. Reapply at least every 2 hours. Use a water resistant sunscreen if swimming or sweating. For use on children less than 6 months of age, consult a health care practitioner.

## CAUTION

For external use only. Do not use on damaged or broken skin. If rash occurs, discontinue use and consult a health care practitioner. Keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed get medical help or contact a Poison Control Centre right away. Do not expose babies and young children directly to the sun. Avoid contact with textiles.

## GARNIER®

Sun protection pioneer since 1936.

## 884366 - Active Ingredients Actifs (w/w):

Homosalate: 10%, Octocrylene: 7%, Octisalate: 5%, Avobenzone: 4%, Drometrizole Trisiloxane (Mexoryl® XL): 2.5%, Terephthalylidene Dicamphor Sulfonic Acid (Mexoryl® SX): 0.5%.

## Others/Autres:

Aqua, Glycerin, Alcohol Denat., Styrene/Acrylates Copolymer, Dimethicone, Propylene Glycol, PEG-100 Stearate, Glyceryl Stearate, Silica, Synthetic Wax, Phenylethanol, Sodium Polyacrylate, Triethanolamine, Stearic Acid, Caprylyl Glycol, Palmitic Acid, PEG-8 Laurate, Xanthan Gum, Tocopherol, Disodium EDTA, Code F.I.L.: K16004/Q3



# GARNIER OMBRELLE SPF 60 COMPLETE LIGHTWEIGHT

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## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:49967-081
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	70 mg in 1 mL
<b>octisalate</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	octisalate	50 mg in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	40 mg in 1 mL
<b>DROMETRIZOLE TRISILOXANE</b> (UNII: HC228451X) (AVOBENZONE - UNII:G63QQF2NOX)	DROMETRIZOLE TRISILOXANE	25 mg in 1 mL
<b>ECAMSULE</b> (UNII: M94R1PM439) (ECAMSULE - UNII:M94R1PM439)	ECAMSULE	5 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>STYRENE/ACRYLAMIDE COPOLYMER (500000 MW)</b> (UNII: 5Z4DPO246A)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>PALMITIC ACID</b> (UNII: 2V16EO95H1)	
<b>PEG-8 LAURATE</b> (UNII: 762O8IWA10)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-081-01	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/16/2014	
2	NDC:49967-081-02	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/16/2014	
3	NDC:49967-081-03	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/16/2014	
4	NDC:49967-081-04	200 mL in 1 PACKAGE; Type 0: Not a Combination Product	12/16/2014	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
export only		12/16/2014	

**Labeler** - L'Oreal USA Products Inc (002136794)

## Establishment

Name	Address	ID/FEI	Business Operations
L'Oreal USA, INC.		624244349	manufacture(49967-081) , pack(49967-081)

