

GARNIER OMBRELLE SPF 45 SPORT- avobenzone, octocrylene, terephthalylidene dicamphor sulfonic acid and titanium dioxide lotion

L'Oreal USA Products Inc

Drug Facts

Active ingredients

Avobenzone 1.5%

Octocrylene 7%

Terephthalylidene Dicamphor Sulfonic Acid 0.5%

Titanium dioxide 3.3%

Warnings

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 Center right away. 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.

Inactive ingredients

water, glycerin, propylene glycol, C12-15 alkyl benzoate, cyclohexasiloxane, alcohol denat., isoheaxadecane, silica, VP/eicosene copolymer, panthenol, poly C10-30 alkyl acrylate, stearic acid, triethanolamine, PEG-100 stearate, glyceryl stearate, phenoxyethanol, potassium cetyl phosphate, dimethicone, aluminum hydroxide, methylparaben, acrylates/C10-30 alkyl acrylate crosspolymer, tocopherol, disodium EDTA, xanthan gum, butylparaben, ethylparaben, isobutylparaben, propylparaben

GARNIER®
OMBRELLE

SPF
FPS
45
LOTION
SPORT

HYPOALLERGENIC
HYPOALLERGÉNIQUE

Oil free / Sans huile
Fragrance free / Sans parfum
Colorant free / Sans colorant

 **MEXORYL®**
TECHNOLOGIE
And other sunscreen filters / Et autres filtres

BROAD-SPECTRUM PROTECTION À LARGE SPECTRE 

Recognized Sun Protection Canadian Dermatology Association  **Reconnu Protection solaire Association canadienne de dermatologie**

200 mL
DIN 02269910

PATENTED BROAD-SPECTRUM UVA-UVB PROTECTION

WITH MEXORYL® TECHNOLOGY

TECHNOLOGY Ombrelle®'s patented filtering system with Mexoryl® technology and other sunscreen filters provides broad-spectrum UVA/UVB protection to help prevent sunburn.

BENEFITS Ombrelle® Sport Lotion SPF 45 is highly recommended for active individuals. It provides UVA/UVB protection for face and body with a non-greasy finish. This hypoallergenic lotion is non-comedogenic, fragrance and colorant free.

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 Center right away. Avoid contact with textiles.

PROTECTION UVA-UVB À LARGE SPECTRE BREVETÉE

AVEC TECHNOLOGIE MEXORYL®

TECHNOLOGIE Le système filtrant breveté de Ombrelle®, avec technologie Mexoryl® et autres filtres solaires, procure une protection UVA/UVB à large spectre efficace pour aider à prévenir les coups de soleil.

BÉNÉFICES Ombrelle® Lotion Sport FPS 45 est hautement recommandée pour les personnes actives. Elle procure une protection UVA/UVB pour le corps et le visage avec un fini non-gras. Cette lotion hypoallergénique est non-comédogène et ne contient ni parfum ni colorant.

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 la 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. Éviter le contact avec les textiles.

736171/6 - Active Ingredients Actifs (w/w): Octocrylene: 7%, Titanium Dioxide: 3.3%, Avobenzone: 1.5%, Terephthalylidene Dicamphor Sulfonic Acid (Mexoryl® SX): 0.6%, Others/Autres: Aqua, Glycerin, Propylene Glycol, C12-15 Alkyl Benzoate, Cyclohexanone, Alcohol Denat., Isohexadecane, Silica, VP/Eicosanol Copolymer, Panthenol, Poly C10-18 Alkyl Acrylate, Stearic Acid, Trithionamine, PEG-100 Stearate, Ricinyl Stearate, Phenoxethanol, Potassium Cetyl Phosphate, Dimethicone, Aluminum Hydroxide, Methylparaben, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Tocopherol, Disodium EDTA, Karitin Gum, Butylparaben, Ethylparaben, Isobutylparaben, Propylparaben. Data F.I.L.: K23554/2

GARNIER®

Sun protection pioneer since 1936.
Pionnier de la protection solaire depuis 1936.

www.ombrelle.ca
1 888 9-OMBREL

Mexoryl® is a registered trademark /
est une marque légalement déposée de L'Oréal S.A.
Inc. by / par Ombrelle Canada, Montréal. H4T 1K6
2048334 • K1146200



GARNIER OMBRELLE SPF 45 SPORT

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Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:49967-566 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 15 mg in 1 mL |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 70 mg in 1 mL |
| ECAMSULE (UNII: M94R1PM439) (ECAMSULE - UNII:M94R1PM439) | ECAMSULE | 5 mg in 1 mL |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 33 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | |
| CYCLOMETHICONE 6 (UNII: XHK3U310BA) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| ISOHEXADECANE (UNII: 918X10UF1E) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3) | |
| PANTHENOL (UNII: WV9CM0O67Z) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) | |
| METHYL PARABEN (UNII: A2I8C7HI9T) | |
| CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| BUTYL PARABEN (UNII: 3QPII03FV8) | |
| ETHYL PARABEN (UNII: 14255EXE39) | |
| ISOBUTYL PARABEN (UNII: 0QJ25X58G) | |
| PROPYL PARABEN (UNII: Z8IX2SC1OH) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:49967-566-01 | 200 mL in 1 TUBE; Type 0: Not a Combination Product | 01/01/2017 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| export only | | 01/01/2017 | |

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------|---------|-----------|--|
| L'OREAL USA, INC. | | 624244349 | manufacture(49967-566) , pack(49967-566) |

