

GARNIER OMBRELLE SPF 50 KIDS WATER RESISTANT- titanium dioxide, octisalate, drometrizole trisiloxane, avobenzone, octocrylene and ecamsule lotion
L'Oreal USA Products Inc

Drug Facts

Active ingredients

Titanium Dioxide 5.85%

Octisalate 5%

Drometrizole Trisiloxane 4.5%

Avobenzone 3%

Octocrylene 2.5%

Ecamsule 1.5%

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 product out of eyes. If contact occurs, 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, after 40 minutes of swimming or sweating and immediately after towel drying. For use on children less than 6 months of age, consult a health care practitioner.

Others

Aqua, C12-15 Alkyl Benzoate, Alcohol Denat., Caprylic/Capric Triglyceride, Isododecane, Propylene Glycol, Dimethicone, Glycerin, PEG-30 Dipolyhydroxystearate, Lauryl PEG/PPG-18/18 Methicone, Synthetic Wax, Ammonium Polyacryloyldimethyl Taurate, Silica, Triethanolamine, Cellulose Gum, Caprylyl Glycol, Dimethicone Crosspolymer, Isostearyl Alcohol, Decedene, Poloxamer 407, Glycine Soja Oil, Tocopherol, Pentasodium Ethylenediamine Tetramethylene Phosphonate, Hydrolyzed Algin, Magnesium Sulfate, Manganese Sulfate, Benzyl Benzoate, Benzyl Alcohol

TECHNOLOGIE

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

BÉNÉFICES

- Umbrelle® Lotion FPS 50+ Enfants est une protection solaire hydratante et résistante à l'eau (40 minutes) conçue spécialement pour la peau délicate de l'enfant.
- Sa texture est facile à appliquer et s'absorbe rapidement par la peau.
- Cette lotion hypoallergénique ne contient ni parfum ni colorant. Sans parabène.
- Si le produit est utilisé selon les instructions et avec d'autres mesures de protection contre le soleil (voir mode d'emploi), le risque de cancer de la peau et de vieillissement prématuré de la peau causé par le soleil est réduit.
- Cette lotion aide à prévenir les coups de soleil.

MODE D'EMPLOI

Appliquer généreusement et uniformément 15 minutes avant exposition au soleil. Appliquer de nouveau au moins toutes les 2 heures, après 40 minutes de baignade ou après avoir transpiré et immédiatement après s'être séché à la serviette. Pour les enfants âgés de moins de 6 mois, consulter un professionnel de la santé.

MESURES DE PROTECTION CONTRE LE SOLEIL

Passer du temps au soleil augmente le risque de cancer de la peau et de vieillissement prématuré de la peau. Afin de diminuer ce risque, il convient d'utiliser régulièrement un écran avec un FPS à large spectre d'au moins 15 et d'appliquer d'autres mesures de protection contre le soleil, telles que: limiter le temps passé au soleil, notamment entre 10 et 14 heures, et porter des chemises à manches longues, des pantalons, un chapeau et des lunettes de soleil.

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. 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 SA, Imp. y / par Umbrelle Canada, Montréal, H4T 1K5

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TECHNOLOGY

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

BENEFITS

- Umbrelle® SPF 50+ Kids lotion is a moisturizing and water resistant (40 minutes) sun protection specifically formulated for a child's delicate skin.
- Its texture is easy to apply and is quickly absorbed by the skin.
- This hypoallergenic lotion is fragrance and colorant free. Paraben free.
- If product is used as directed with other sun protection measures (see directions for use), it decreases the risk of skin cancer and early skin aging caused by the sun.
- This lotion helps prevent sunburn.

DIRECTIONS

Apply generously and evenly 15 minutes before sun exposure. Reapply at least every 2 hours, after 40 minutes of swimming or sweating and immediately after towel drying. For use on children less than 6 months of age, consult a health care practitioner.

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 15 or higher and other sun protection measures including: limiting time in the sun, especially from 10 am - 2 pm, and wearing long-sleeved shirts, pants, hats and sunglasses.

CAUTION

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GARNIER®

Sun protection pioneer since 1936.

858371 - Active Ingredients Actifs (w/w):

Titanium Dioxide: 5.65%, Octisalate: 5%, Drometrizole Trisiloxane (Mexoryl® XL): 4.5%, Avobenzone: 3%, Octocrylene: 2.5%, Ecamsule (Mexoryl® SX): 1.5%.

Others/Autres:

Aqua, C12-15 Alkyl Benzoate, Alcohol Denat., Caprylic/Capric Triglyceride, Isododecane, Propylene Glycol, Dimethicone, Glycerin, PEG-30 Dipolyhydroxyesterate, Lauryl PEG/PPG-10/18 Methicone, Synthetic Wax, Ammonium Polyacryloyldimethyl Taurate, Silica, Triethanolamine, Cellulose Gum, Caprylyl Glycol, Dimethicone Crosspolymer, Isostearyl Alcohol, Dodecane, Poloxamer 407, Glycine Soja Oil, Tocopherol, Pentasodium Ethylenediamine Tetramethylene Phosphonate, Hydrolyzed Alginate, Magnesium Sulfate, Manganese Sulfate, Benzyl Benzoate, Benzyl Alcohol, Code F.I.L.: C164447/4



GARNIER OMBRELLE SPF 50 KIDS WATER RESISTANT

titanium dioxide, octisalate, drometrizole trisiloxane, avobenzone, octocrylene and ecamsule lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-469
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	58.5 mg in 1 mL
Octisalate (UNII: 4X49 Y059 6 W) (OCTISALATE - UNII:4X49 Y059 6 W)	Octisalate	50 mg in 1 mL
DROMETRIZOLE TRISILOXANE (UNII: HC228451IX) (DROMETRIZOLE TRISILOXANE - UNII:HC228451IX)	DROMETRIZOLE TRISILOXANE	45 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	25 mg in 1 mL
ECAMSULE (UNII: M94R1PM439) (ECAMSULE - UNII:M94R1PM439)	ECAMSULE	15 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ALCOHOL (UNII: 3K9958V90M)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ISODODECANE (UNII: A8289P68Y2)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
ISOSTEARYL ALCOHOL (UNII: Q6130CQ44Y)	
DODECENE (UNII: WYE669F3GR)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
LEXIDRONAM PENTASODIUM (UNII: 2ZYX2V82AD)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
MANGANESE SULFATE (UNII: W00LYS4T26)	
BENZYL BENZOATE (UNII: N863NB338G)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-469-01	120 in 1 CARTON	07/28/2015	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49967-469-02	240 in 1 CARTON	07/28/2015	
2		240 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
export only		07/28/2015	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
L'Oreal USA, Inc.		624244349	manufacture(49967-469) , pack(49967-469)

