

**GARNIER OMBRELLE SPF 30 KIDS WATER RESISTANT- oxybenzone, octisalate, octocrylene, titanium dioxide, avobenzone and terephthalylidene dicamphor sulfonic acid lotion**  
L'Oreal USA Products Inc

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**Drug Facts**

**Active ingredients**

Oxybenzone 5%

Octisalate 5%

Octocrylene 3.5%

Titanium Dioxide 3.3%

Avobenzone 3%

Terephthalylidene Dicamphor Sulfonic Acid 1%

**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.

**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 of children less than 6 months of age, consult a health care practitioner.

**Others**

Aqua, Glycerin, Dicaprylyl Carbonate, Propylene Glycol, Alcohol Denat., Hydrogenated Polyisobutene, Triethanolamine, VP/Eicosene Copolymer, Dimethicone, Isohexadecane, Panthenol, Stearic Acid, Phenoxyethanol, PEG-100 Stearate, Glyceryl Stearate, Aluminum Hydroxide, Methylparaben, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Tocopherol, Disodium EDTA, Xanthan Gum, Butylparaben, Ethylparaben, Isobutylparaben, Propylparaben

## TECHNOLOGIE

Le système filtrant breveté de Ombrelle® avec la 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 FPS 30 pour enfants est une protection solaire douce et hydratante conçue spécialement pour la peau délicate de l'enfant.
- Cette lotion procure une protection UVA-UVB à large spectre et est résistante à l'eau (40 minutes) pour protéger efficacement pendant que les enfants sont actifs.
- Sa texture légère est facile à appliquer et s'absorbe rapidement sur la peau.
- Cette lotion hypoallergénique est non comédogène et ne contient ni parfum ni colorant. Sans PABA.
- Les écrans solaires que contient ce produit répondent à aux critères établis par l'Association canadienne de dermatologie.

## MODE D'EMPLOI

Appliquer généreusement et uniformément 15 minutes avant l'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.

## 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.

## GARNIER®

Pionnier de la protection solaire depuis 1936.

www.ombrelle.ca  
1 888 9-OMBREL

Parasol® 1789 is a registered trademark of / est une marque déposée de DSM IP Assets B.V. Mexoryl® is a registered trademark / est une marque de commerce déposée de L'Oréal S.A. Imp. by / par Ombrelle Canada, Montreal H4T 1K5 2030834 K1055601 \*Et autres filtres solaires.

## TECHNOLOGY

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

## BENEFITS

- Ombrelle® Kids Lotion SPF 30 is a gentle and moisturizing sun protection specifically formulated for a child's delicate skin.
- This lotion provides broad-spectrum UVA-UVB protection and is water resistant (40 minutes) to effectively protect while children are active.
- Its light texture is easy to apply and is quickly absorbed by the skin.
- This hypoallergenic lotion is non-comedogenic, fragrance and colorant free. PABA free.
- The sunscreens in this product meet the criteria established by the Canadian Dermatology Association.

## 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.

## 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.

## GARNIER®

Sun protection pioneer since 1936.

## 293636/4 - Active Ingredients Actifs (w/w)

Oxybenzone: 5%, Octisalate: 5%, Octocrylene: 3.5%, Titanium Dioxide: 3.3%, Avobenzone (Parasol® 1789): 3%, Terephthalidene Dicamphor Sulfonic Acid (Mexoryl® SX): 1%.

## Others/Autres:

Aqua, Glycerin, Dicaprylyl Carbonate, Propylene Glycol, Alcohol Denat., Hydrogenated Polyisobutene, Triethanolamine, VP/Eicosene Copolymer, Dimethicone, Isohexadecane, Panthenol, Stearic Acid, Phenylethanol, PEG-100 Stearate, Glyceryl Stearate, Aluminum Hydroxide, Methylparaben, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Tocopherol, Disodium EDTA, Xanthan Gum, Butylparaben, Ethylparaben, Isobutylparaben, Propylparaben. Code F.I.L.: K4347/2 \*And other sunscreen filters.

## GARNIER OMBRELLE SPF 30 KIDS WATER RESISTANT

oxybenzone, octisalate, octocrylene, titanium dioxide, avobenzone and terephthalidene dicamphor sulfonic acid lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-462
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 9500S7VE0 Y) (OXYBENZONE - UNII:9500S7VE0 Y)	OXYBENZONE	50 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	35 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	33 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
ECAMSULE (UNII: M94R1PM439) (ECAMSULE - UNII:M94R1PM439)	ECAMSULE	10 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)
GLYCERIN (UNII: PDC6A3C0OX)
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
ALCOHOL (UNII: 3K9958V90M)
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)
TROLAMINE (UNII: 9O3K93S3TK)
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)
DIMETHICONE (UNII: 92RU3N3Y1O)
ISOHEXADECANE (UNII: 918X1OUF1E)
PANTHENOL (UNII: WV9CM0O67Z)
STEARIC ACID (UNII: 4ELV7Z65AP)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
PEG-100 STEARATE (UNII: YD01N1999R)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
METHYLPARABEN (UNII: A2I8C7HI9T)
TOCOPHEROL (UNII: R0ZB2556P8)
EDETATE DISODIUM (UNII: 7FLD91C86K)
XANTHAN GUM (UNII: TTV12P4NEE)
BUTYLPARABEN (UNII: 3QPI1U3FV8)
ETHYLPARABEN (UNII: 14255EXE39)
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)
PROPYLPARABEN (UNII: Z8IX2SC1OH)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-462-01	1 in 1 CARTON	10/12/2011	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49967-462-02	1 in 1 CARTON	10/12/2011	
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		10/12/2011	

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

### Establishment

Name	Address	ID/FEI	Business Operations
L'Oreal USA, Inc.		624244349	manufacture(49967-462) , pack(49967-462)