

# **GARNIER OMBRELLE FACE MINERAL 50- titanium dioxide and zinc oxide lotion**

## **L'OREAL USA PRODUCTS INC**

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### **Drug Facts**

#### **Active ingredients**

Titanium dioxide 9.02%

Zinc oxide 7%

#### **Warnings**

For external use only. When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. Do not use on broken skin. Stop use and ask a doctor if rash occurs. Other warnings. Keep out of reach of children. If swallowed get medical help or contact a poison control center right away.

#### **Directions**

Adults and children over 6 months and up. Apply generously and evenly 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 11 a.m to 3 p.m. and wear long-sleeve shirts, pants, hats and sunglasses.

#### **Inactive ingredients**

water, glycerin, c12-15 alkyl benzoate, dimethicone, isododecane, styrene/acrylates copolymer, glyceryl stearate, butyloctyl salicylate, dicaprylyl carbonate, propanediol, stearic acid, aluminum hydroxide, PEG-100 stearate, sorbitan stearate, niacinamide, cetearyl alcohol, phenoxyethanol, panthenol, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, PEG-8 laurate, palmitic acid, caprylyl glycol, polyhydroxystearic acid, cetareth-20, sodium citrate, chlorphenesin, citric acid, xanthan gum, triethoxycaprylsilane, dimethiconol, sodium dodecylbenzenesulfonate, myristic acid, sorbitan isostearate, polysorbate 60, sodium hyaluronate, tocopherol



GARNIER®  
**OMBRELLE®**

FILTRES SOLAIRES 100 % MINÉRAUX

VISAGE  
**MINÉRALE**

ÉCRAN SOLAIRE  
**LOTION HYDRATANTE**  
HYPOALLERGÉNIQUE

UVA+UVB

SPF  
**50**

PROTECTION  
À LARGE SPECTRE

Convient aux peaux sensibles  
Sans parfum ni colorant  
Non comédogène



75 ml

NPN 80097042

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Keep out of reach of children.  
If swallowed, call a poison control centre or get medical help right away.

**Directions** Adults and children 6 months and up. Apply generously and evenly 15 minutes before sun exposure. Reapply at least every 2 hours. Use a water resistant sunscreen if swimming or sweating.

Sun Protection Measure 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 11 a.m. – 3 p.m.; and wear long-sleeved shirts, pants, hats, and sunglasses.

**Active ingredients (w/w) / Ingrédients actifs (p/p)**  
Titanium Dioxide 99%, Zinc Oxide 7%.

**Non medicinal ingredients / Ingrédients non médicinaux**  
Aqua, glycerin, c12-15 alkyl benzoate, dimethicone, isododecane, styrene/acrylates copolymer, glyceryl stearate, butyloctyl salicylate, dicaprylyl carbonate, propenediol, stearic acid, aluminum hydroxide, PEG-100 stearate, pentolin stearate, niacinamide, cetearyl alcohol, phenoxyethanol, penthenol, hydroxyethyl acrylate/sodium acryloyldimethyl laurate copolymer, PEG-8 laurate, palmitic acid, caprylyl glycol, polyhydroxystearic acid, ceteareth-20, sodium citrate, chlorphenesin, citric acid, certhan gum, methoxycaprylylbisane, dimethiconol, sodium dodecylbenzenesulfonate, myristic acid, sorbitan isostearate, polyisobutylate 80, sodium hyaluronate, tocopherol.  
F.M.L. 919114  
Code F.L.L. 02482228



GARNIER®  
**OMBRELLE®**

100% MINERAL SUN FILTERS

FACE  
**MINERAL**

SUNSCREEN  
HYPOALLERGENIC  
**HYDRATING LOTION**

UVA+UVB

SPF  
**50**

BROAD-SPECTRUM  
PROTECTION

Suitable for sensitive skin  
Fragrance and colorant free  
Non-comedogenic



75 ml

NPN 80097042

**Mise en garde**  
Pour usage externe seulement.  
Ne pas utiliser sur une peau éraillée.  
Lorsque vous utilisez ce produit éviter tout contact avec les yeux.  
Le cas échéant, bien rincer avec de l'eau.  
Cessez d'utiliser et consultez un médecin si une éruption cutanée se développe.  
Garder hors de la portée des enfants. En cas d'ingestion, appeler immédiatement un centre antipoison ou obtenir une assistance médicale.

**Mode d'emploi** Adultes et enfants 6 mois et plus. Appliquez généreusement et uniformément 15 minutes avant l'exposition au soleil. Appliquez de nouveau au moins toutes les 2 heures. Utilisez un écran solaire résistant à l'eau lors d'une activité aquatique ou s'il y a transpiration.

Mesure de protection contre le soleil. Passer du temps au soleil augmente le risque de cancer de la peau et du vieillissement prématuré de la peau. Afin de diminuer ce risque, il convient d'utiliser régulièrement un écran solaire 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 11 h – 15 h ; et porter des chemises à manches longues, des pantalons, un chapeau et des lunettes de soleil.

GARNIER®

www.ombrelle.ca

Questions? 1 888 766-2735 (9-OMBRELLE)

05289993

Imp. by/par Ombrelle Canada,

Montreal, Q.T. H5S

LOT XXXX

EXP. DATE



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OMBRELLE®**

**FILTRES SOLAIRES 100 % MINÉRAUX**

**VISAGE  
MINÉRALE**

ÉCRAN SOLAIRE  
**LOTION HYDRATANTE**  
HYPOALLERGÉNIQUE

UVA+UVB **SPF 50**  
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F.M.L. 919114  
Code F.L.L. 02488228



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OMBRELLE®**

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**FACE  
MINERAL**

SUNSCREEN  
**HYPOALLERGENIC**  
**HYDRATING LOTION**

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0528993  
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Montreal, Q.T. 1K5

LOT XXXX  
EXP. DATE XXXX

C1 - Internal use

**GARNIER OMBRELLE FACE MINERAL 50**

titanium dioxide and zinc oxide lotion

## Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:49967-850 |
| Route of Administration | TOPICAL        |                    |               |

## Active Ingredient/Active Moiety

| Ingredient Name                                                                 | Basis of Strength | Strength        |
|---------------------------------------------------------------------------------|-------------------|-----------------|
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE  | 90.2 mg in 1 mL |
| <b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)             | ZINC OXIDE        | 70 mg in 1 mL   |

## Inactive Ingredients

| Ingredient Name                                                                                                  | Strength |
|------------------------------------------------------------------------------------------------------------------|----------|
| <b>WATER</b> (UNII: 059QF0KO0R)                                                                                  |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                                                               |          |
| <b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)                                                                |          |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)                                                                            |          |
| <b>ISODODECANE</b> (UNII: A8289P68Y2)                                                                            |          |
| <b>STYRENE/ACRYLAMIDE COPOLYMER (500000 MW)</b> (UNII: 5Z4DPO246A)                                               |          |
| <b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)                                                                  |          |
| <b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)                                                                  |          |
| <b>DICAPRYLYL CARBONATE</b> (UNII: 609A3V1SUA)                                                                   |          |
| <b>PROPANEDIOL</b> (UNII: 5965N8W85T)                                                                            |          |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)                                                                           |          |
| <b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)                                                                     |          |
| <b>PEG-100 STEARATE</b> (UNII: YD01N1999R)                                                                       |          |
| <b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X)                                                                  |          |
| <b>NIACINAMIDE</b> (UNII: 25X51I8RD4)                                                                            |          |
| <b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)                                                                    |          |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                                                                         |          |
| <b>PANTHENOL</b> (UNII: WW9CM0O67Z)                                                                              |          |
| <b>HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%)</b> (UNII: 86FQE96TZ4) |          |
| <b>PEG-8 LAURATE</b> (UNII: 762O8IWA10)                                                                          |          |
| <b>PALMITIC ACID</b> (UNII: 2V16EO95H1)                                                                          |          |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                                                                        |          |
| <b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)                                                      |          |
| <b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)                                                          |          |
| <b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)                                                                         |          |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)                                                                          |          |
| <b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)                                                                |          |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)                                                                            |          |
| <b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)                                                                |          |
| <b>DIMETHICONOL (70 CST)</b> (UNII: MOT8IL21AR)                                                                  |          |
| <b>SODIUM DODECYLBENZENESULFONATE</b> (UNII: 554127163Y)                                                         |          |
| <b>MYRISTIC ACID</b> (UNII: 0I3V7S25AW)                                                                          |          |
| <b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)                                                                   |          |

| <b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)     |                  |                                                      |                      |                    |
|----------------------------------------------|------------------|------------------------------------------------------|----------------------|--------------------|
| <b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH) |                  |                                                      |                      |                    |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)         |                  |                                                      |                      |                    |
|                                              |                  |                                                      |                      |                    |
| <b>Packaging</b>                             |                  |                                                      |                      |                    |
| #                                            | Item Code        | Package Description                                  | Marketing Start Date | Marketing End Date |
| 1                                            | NDC:49967-850-01 | 1 in 1 CARTON                                        | 02/09/2021           |                    |
| 1                                            |                  | 75 mL in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |
|                                              |                  |                                                      |                      |                    |
| <b>Marketing Information</b>                 |                  |                                                      |                      |                    |
| Marketing Category                           |                  | Application Number or Monograph Citation             | Marketing Start Date | Marketing End Date |
| export only                                  |                  |                                                      | 02/09/2021           |                    |

**Labeler -** L'OREAL USA PRODUCTS INC (002136794)

## Establishment

| Name             | Address | ID/FEI    | Business Operations                      |
|------------------|---------|-----------|------------------------------------------|
| L'OREAL USA, INC |         | 624244349 | manufacture(49967-850) , pack(49967-850) |

Revised: 1/2026

L'OREAL USA PRODUCTS INC