

CLE DE PEAU BEAUTE RADIANT FLUID FOUNDATION O70- octinoxate and titanium dioxide emulsion

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SHISEIDO AMERICAS CORPORATION

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

CLÉ DE PEAU BEAUTÉ RADIANT FLUID FOUNDATION

Drug Facts

| <i>Active ingredients</i> | <i>Purpose</i> |
|----------------------------------|-----------------------|
| Octinoxate 4.9% | Sunscreen |
| Titanium Dioxide 2.5% | Sunscreen |

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- Use a water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- **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 of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. – 2 p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses
 - children under 6 months: Ask a doctor

Inactive Ingredients

DIMETHICONE•WATER•BUTYLENE GLYCOL•GLYCERIN•PEG-10
DIMETHICONE•CYCLOHEXASILOXANE•BIS-BUTYLDIMETHICONE POLYGLYCERYL-
3•POLYMETHYLSILSESQUIOXANE•ERYTHRITOL•XYLITOL•BARIUM

SULFATE•DIPHENYLSILOXY PHENYL TRIMETHICONE•DIMETHICONE/VINYL
DIMETHICONE CROSSPOLYMER•POLYQUATERNIUM-51•SODIUM ACETYLATED
HYALURONATE•ROSA ROXBURGHII FRUIT EXTRACT•HYDROLYZED CONCHIOLIN
PROTEIN•HYDROLYZED SILK•SYNTHETIC FLUORPHLOGOPITE•DIMETHICONE/PEG-10/15
CROSSPOLYMER•DISTEARDIMONIUM HECTORITE•SORBITAN
SESQUIESTEARATE•ALUMINUM HYDROXIDE•STEARIC ACID•DISODIUM
EDTA•POLYSILICONE-
2•ALUMINA•TRIETHOXYCAPRYLYLSILANE•TRIETHOXSILYLETHYL
POLYDIMETHYLSILOXYETHYL DIMETHICONE•TOCOPHEROL•DIPROPYLENE
GLYCOL•SILICA•VINYL DIMETHICONE/METHICONE SILSESQUIOXANE
CROSSPOLYMER•BHT•ALCOHOL•PHENOXYETHANOL•FRAGRANCE•IRON
OXIDES•TITANIUM DIOXIDE•MICA•

Other information

Protect this product in this container from excessive heat and direct sun.

Questions or comments?

Call toll free 1-800-906-7503

PRINCIPAL DISPLAY PANEL - 30 mL Tube Carton - 58411-477

clé de peau
BEAUTÉ

radiant fluid foundation

BROAD SPECTRUM
SPF 24
SUNSCREEN

30mL 1 FL. OZ.

radiant fluid foundation

O70

radiant fluid foundation

O80

clé de peau
BEAUTÉ
RADIANT FLUID FOUNDATION
BROAD SPECTRUM SPF 24
SUNSCREEN

O70

READ INSERTION.

Drug Facts

Active ingredients

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SHISEIDO AMERICAS
CORPORATION DIST.
NEW YORK, NY 10017
MADE IN U.S.A.
G.L.O. 15819

www.cledepeau-beaute.com

This package is made using bagasse paper (a non-wood paper).

7 30852 15819 1



Drug Facts
(continued)

Warnings

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Directions

For sunscreen use:

■ apply liberally 15 minutes before sun exposure

■ use a water resistant sunscreen if swimming or sweating

■ reapply at least every 2 hours

■ **Sun Protection Measures.**

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SPF 24
SUNSCREEN

30mL 1 FL. OZ.

15819-41-5040
AAA

Drug Facts
(continued)

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DIMETHICONE - WATER - BUTYLENE GLYCOL - GLYCERIN - PEG-10 DIMETHICONE - CYCLOHEXASILOXANE - BIS-BUTYLDIMETHICONE POLYGLYCERYL-3 - POLYMETHYLSILSESQUIOXANE - ERYTHRITOL - XYLITOL - BARIUM SULFATE - DIPHENYLSILOXY PHENYL TRIMETHICONE - DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER - POLYQUATERNIUM-51 - SODIUM ACETYLATED HYALURONATE - ROSA ROXBURGHII FRUIT EXTRACT - HYDROLYZED CONCHOLIN PROTEIN - HYDROLYZED SILK - SYNTHETIC FLUOROPHLOGOPITE - DIMETHICONE/PEG-10/15 CROSSPOLYMER - DISTEARDMONIUM HECTORITE - SORBITAN SESQUISOESTEARATE - ALUMINUM HYDROXIDE - STEARIC ACID - DISODIUM EDTA - POLYSILOXANE-2 - ALLUMINA - TRIETHOXYCAPRYLSILANE - TRIETHOXYSILYLETHYL POLYDIMETHYLSILOXYETHYL DIMETHICONE - TOCOPHEROL - DIPROPYLENE GLYCOL - SILICA - VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER - BHT - ALCOHOL - PHENOXYETHANOL - FRAGRANCE - IRON OXIDES - TITANIUM DIOXIDE - MICA -

Other Information

■ protect this product in this container from excessive heat and direct sun,

Questions or Comments?

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Reducing the quantity of application will lower the level of sunscreen protection significantly.

clé de peau
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RADIANT FLUID FOUNDATION
BROAD SPECTRUM SPF 24
SUNSCREEN

O80

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15820-41-5040
AAA

PRINCIPAL DISPLAY PANEL - 30 mL Tube Carton - 58411-478

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BROAD SPECTRUM

SPF 24

SUNSCREEN

30mL 1 FL. OZ.

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15820-41-5040
AAA

CLE DE PEAU BEAUTE RADIANT FLUID FOUNDATION O70

octinoxate and titanium dioxide emulsion

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58411-477 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 1.6611 g in 30 mL |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 0.8475 mg in 30 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| WATER (UNII: 059QF0KO0R) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0) | |
| CYCLOMETHICONE 6 (UNII: XHK3U310BA) | |
| POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69) | |
| ERYTHRITOL (UNII: RA96B954X6) | |
| XYLITOL (UNII: VCQ006KQ1E) | |
| BARIUM SULFATE (UNII: 25BB7EKE2E) | |
| DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12) | |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) | |
| POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J) | |
| SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93) | |
| ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF) | |
| DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L) | |
| SORBITAN SESQUISO STEARATE (UNII: VU97D01BF9) | |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| ALUMINUM OXIDE (UNII: LM26O6933) | |
| TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E) | |
| .ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) | |
| DIPROPYLENE GLYCOL (UNII: E107L85C40) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| VINYL DIMETHICONE/METHICONE SILSESQUOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR) | |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |

| | |
|--|--|
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |
| FERROSO FERRIC OXIDE (UNII: XM0M87F357) | |
| MICA (UNII: V8A1AW0880) | |

| Packaging | | | | |
|------------------|------------------|---|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:58411-477-20 | 1 in 1 CARTON | 05/01/2019 | |
| 1 | | 30 mL in 1 CARTRIDGE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|------------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part352 | 05/01/2019 | |

CLE DE PEAU BEAUTE RADIANT FLUID FOUNDATION O80

octinoxate and titanium dioxide emulsion

| Product Information | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58411-478 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|-------------------|--------------------|
| Ingredient Name | Basis of Strength | Strength |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 1.6611 g in 30 mL |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 0.8475 mg in 30 mL |

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| PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0) | |
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| POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J) | |
| SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93) | |

| |
|---|
| ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF) |
| DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L) |
| SORBITAN SESQUISO STEARATE (UNII: VU97D01BF9) |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) |
| STEARIC ACID (UNII: 4ELV7Z65AP) |
| EDETATE DISODIUM (UNII: 7FLD91C86K) |
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| TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E) |
| .ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) |
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| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) |
| VINYL DIMETHICONE/METHICONE SILSESQUOXANE CROSSPOLYMER (UNII: 9NHIUDD2RR) |
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Marketing Information

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|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352 | 05/01/2019 | |

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|--|
| SHISEIDO AMERICAS INC. | | 782677132 | MANUFACTURE(58411-477, 58411-478) , ANALYSIS(58411-477, 58411-478) |

Revised: 11/2019

SHISEIDO AMERICAS CORPORATION