

SHADE AND ILLUMINATE SOFT RAD PRMR SPF- octinoxate, octisalate, zinc oxide cream
TOM FORD BEAUTY DIST

SHADE AND ILLUMINATE SOFT RAD PRMR SPF

Active Ingredients

Octinoxate 6.7%

Octisalate 4.5%

Zinc Oxide 10.0%

Purpose

Sunscreen

USE

Helps prevent sunburn

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 and evenly 15 minutes before sun exposure

- reapply at least every two 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 10 a.m. – 2 p.m.
- wear long-sleeved shirts, pants hats and sunglasses
- children under 6 months of age: ask a doctor

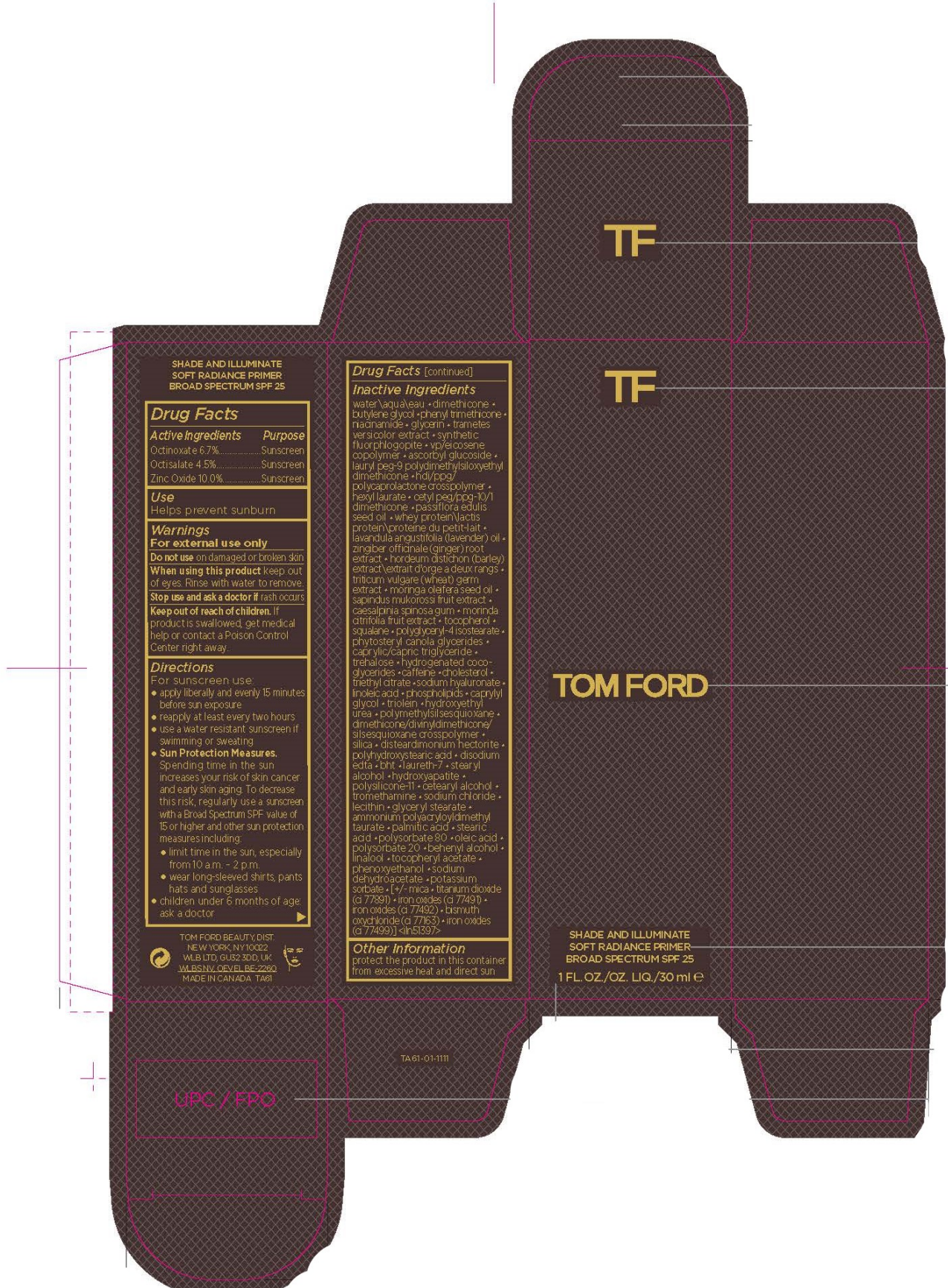
Inactive Ingredients

WATER\AQUA\EAU [] DIMETHICONE [] BUTYLENE GLYCOL [] PHENYL TRIMETHICONE [] NIACINAMIDE [] GLYCERIN [] TRAMETES VERSICOLOR EXTRACT [] SYNTHETIC FLUORPHLOGOPITE [] VP/EICOSENE COPOLYMER [] ASCORBYL GLUCOSIDE [] LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE [] HDI/PPG/POLYCAPROLACTONE CROSSPOLYMER [] HEXYL LAURATE [] CETYL PEG/PPG-10/1 DIMETHICONE [] PASSIFLORA EDULIS SEED OIL [] WHEY PROTEIN\LACTIS PROTEIN\PROTEINE DU PETIT-LAIT [] LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL [] ZINGIBER OFFICINALE (GINGER) ROOT EXTRACT [] HORDEUM DISTICHON (BARLEY) EXTRACT\EXTRAIT D'ORGE A DEUX RANGS [] TRITICUM VULGARE (WHEAT) GERM EXTRACT [] MORINGA OLEIFERA SEED OIL [] SAPINDUS MUKOROSI FRUIT EXTRACT [] CAESALPINIA SPINOSA GUM [] MORINDA CITRIFOLIA FRUIT EXTRACT [] TOCOPHEROL [] SQUALANE [] POLYGLYCERYL-4 ISOSTEARATE [] PHYTOSTERYL CANOLA GLYCERIDES [] CAPRYLIC/CAPRIC TRIGLYCERIDE [] TREHALOSE [] HYDROGENATED COCO-GLYCERIDES [] CAFFEINE [] CHOLESTEROL [] TRIETHYL CITRATE [] SODIUM HYALURONATE [] LINOLEIC ACID [] PHOSPHOLIPIDS [] CAPRYLYL GLYCOL [] TRIOLEIN [] HYDROXYETHYL UREA [] POLYMETHYLSILSESQUIOXANE [] DIMETHICONE/DIVINYLDIMETHICONE/SILSESQUIOXANE CROSSPOLYMER [] SILICA [] DISTEARDIMONIUM HECTORITE [] POLYHYDROXYSTEARIC ACID [] DISODIUM EDTA [] BHT [] LAURETH-7 [] STEARYL ALCOHOL [] HYDROXYAPATITE [] POLYSILICONE-11 [] CETEARYL ALCOHOL [] TROMETHAMINE [] SODIUM CHLORIDE [] LECITHIN [] GLYCERYL STEARATE [] AMMONIUM POLYACRYLOYLDIMETHYL TAURATE [] PALMITIC ACID [] STEARIC ACID [] POLYSORBATE 80 [] OLEIC ACID [] POLYSORBATE 20 [] BEHENYL ALCOHOL [] LINALOOL [] TOCOPHERYL ACETATE [] PHENOXYETHANOL [] SODIUM DEHYDROACETATE [] POTASSIUM SORBATE [] [+/- MICA [] TITANIUM DIOXIDE (CI 77891) [] IRON OXIDES (CI 77491) [] IRON OXIDES (CI 77492) [] BISMUTH OXYCHLORIDE (CI 77163) [] IRON OXIDES (CI 77499)] <ILN51397>

Other Information

protect the product in this container
from excessive heat and direct sun

PRINCIPAL DISPLAY PANEL



SHADE AND ILLUMINATE
SOFT RADIANCE PRIMER
BROAD SPECTRUM SPF 25

Drug Facts

| Active Ingredients | Purpose |
|--------------------|-----------|
| Octinoxate 6.7% | Sunscreen |
| Octisalate 4.5% | Sunscreen |
| Zinc Oxide 10.0% | Sunscreen |

Use

Helps prevent sunburn

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

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Directions

For sunscreen use:

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- reapply at least every two 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 10 a.m. - 2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses
- children under 6 months of age, ask a doctor

TOM FORD BEAUTY, DIST.
NEW YORK, NY 10022
WLB LTD, OUS2 3DD UK
WLBSSNV, OEVBL, BE226Q
MADE IN CANADA TA61



Drug Facts [continued]

Inactive Ingredients

water/aqua/eau • dimethicone • butylene glycol • phenyl trimethicone • niacinamide • glycerin • triethoxycellulose • panthenol • synthetic fluoroaluminum silicate • polydimethylsiloxane copolymer • ascorbyl glucoside • lauryl peg-9 polydimethylsiloxyethyl dimethicone • hd/peg/ polycaprolactone crosspolymer • hexyl laurate • cetyl peg/ppg-10/1 dimethicone • passiflora edulis seed oil • wheat protein/actis protein/proteine du petit-lait • lavandula angustifolia (lavender) oil • zingiber officinale (ginger) root extract • hordeum distichon (barley) extract/extrait d'orge a deux rangs • triticum vulgare (wheat) germ extract • moringa oleifera seed oil • spandus mukorossi fruit extract • caesalpinia sponosa gum • morinda citrifolia fruit extract • tocopherol • squalane • polyglyceryl-4 isostearate • phytosteril • canola glycerides • caprylic/capric triglyceride • trehalose • hydrogenated cocoglycerides • caffeine • cholesterol • methyl citrate • sodium hyaluronate • inoleic acid • phospholipids • caprylyl glycol • triolein • hydroxyethyl urea • polymethylsilsesquioxane • dimethicone/divinyl dimethicone/silsesquioxane crosspolymer • silica • disteardimonium Hectorite • polyhydroxystearic acid • disodium edta • bht • laureth-7 • stearyl alcohol • hydroxyapatite • polysilicone-11 • cetearyl alcohol • tromethamine • sodium chloride • lecithin • glyceryl stearate • ammonium polyacryloyldimethyl taurate • palmitic acid • stearic acid • polysorbate 80 • oleic acid • polysorbate 20 • behenyl alcohol • linalool • tocopheryl acetate • phenoxyethanol • sodium dehydroacetate • potassium sorbate • +/- mica • titanium dioxide (ci 77891) • iron oxides (ci 77491) • iron oxides (ci 77492) • bismuth oxychloride (ci 77163) • iron oxides (ci 77499) • cin5397

Other Information

protect the product in this container from excessive heat and direct sun

TF

TF

TOM FORD

SHADE AND ILLUMINATE
SOFT RADIANCE PRIMER
BROAD SPECTRUM SPF 25

1 FL. OZ./OZ. LIQ./30 ml e

TA61-01-1111

UPC / FPO

TOM FORD

SHADE AND ILLUMINATE
SOFT RADIANCE PRIMER
BROAD SPECTRUM SPF 25
1 FL. OZ./OZ. LIQ./30 ml e

SHADE AND ILLUMINATE SOFT RAD PRMR SPF

octinoxate,octisalate,zinc oxide cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76398-013 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 100 mg in 1 mL |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 67 mg in 1 mL |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 45 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| TREHALOSE (UNII: B8WCK70T7I) | |
| CAFFEINE (UNII: 3G6A5W338E) | |
| CHOLESTEROL (UNII: 97C5T2UQ7J) | |
| MORINGA OLEIFERA SEED OIL (UNII: REM6A5QMC0) | |
| SAPINDUS MUKOROSI FRUIT (UNII: 66H9NW427Y) | |
| CAESALPINIA SPINOSA RESIN (UNII: WL3883U2PO) | |
| MORINDA CITRIFOLIA FRUIT (UNII: 7829X3G2X5) | |
| POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7) | |
| TRAMETES VERSICOLOR FRUITING BODY (UNII: 4C900477MT) | |
| LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA) | |
| OLEIC ACID (UNII: 2UMI9U37CP) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| MICA (UNII: V8A1AW0880) | |
| FERROSFERRIC OXIDE (UNII: XM0M87F357) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |

| | |
|--|--|
| LAVENDER OIL (UNII: ZBP1YXW0H8) | |
| LINOLEIC ACID (UNII: 9KJL21T0QJ) | |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| HEXYL LAURATE (UNII: 4CG9F9W01Q) | |
| GINGER (UNII: C5529G5JPQ) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| HYDROGENATED COCO-GLYCERIDES (UNII: XDD37N2GPR) | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) | |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| SQUALANE (UNII: GW89575KF9) | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | |
| DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L) | |
| SODIUM DEHYDROACETATE (UNII: 8W46YN971G) | |
| BISMUTH OXYCHLORIDE (UNII: 4ZR792I587) | |
| WATER (UNII: 059QF0KO0R) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT) | |
| PASSIFLORA EDULIS SEED OIL (UNII: F3VOA31UHQ) | |
| WHEY (UNII: 8617Z5FMF6) | |
| BARLEY (UNII: 5PVM7YLI7R) | |
| WHEAT GERM (UNII: YR3G369F5A) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| GLYCERYL TRIOLEATE (UNII: O05EC62663) | |
| HYDROXYETHYL UREA (UNII: MBQ7DDQ7AR) | |
| POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69) | |
| DIMETHICONE/DIVINYLDIMETHICONE/SILSESQUIOXANE CROSSPOLYMER (UNII: T3064TZ75A) | |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) | |
| LAURETH-7 (UNII: Z95S6G8201) | |
| TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28) | |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) | |
| TROMETHAMINE (UNII: 023C2WHX2V) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| AMMONIUM POLYACRYLOYLDIMETHYL TAURATE (55000 MPA.S) (UNII: F01RIY4371) | |
| PALMITIC ACID (UNII: 2V16EO95H1) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| DOCOSANOL (UNII: 9G1OE216XY) | |
| LINALOOL, (+/-)- (UNII: D81QY6I88E) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |

| | |
|---|--|
| PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R) | |
| NIACINAMIDE (UNII: 25X51I8RD4) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| EICOSYL POVIDONE (UNII: XQQ9MKE2BJ) | |
| ASCORBYL GLUCOSIDE (UNII: 2V52R0NHXW) | |

| Packaging | | | | |
|------------------|------------------|---|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:76398-013-01 | 1 in 1 CARTON | 10/14/2022 | |
| 1 | | 30 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:76398-013-02 | 1 in 1 CARTON | 10/14/2022 | 11/30/2023 |
| 2 | | 3.6 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 |
| OTC Monograph Drug | M020 | 10/14/2022 | |

Labeler - TOM FORD BEAUTY DIST (005914387)

Registrant - Estee Lauder Companies Inc. (790802086)

| Establishment | | | |
|-----------------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| Estee Lauder Cosmetics Ltd. | | 202952982 | manufacture(76398-013) |

| Establishment | | | |
|-----------------------------|---------|-----------|------------------------------------|
| Name | Address | ID/FEI | Business Operations |
| Estee Lauder Cosmetics Ltd. | | 204132062 | pack(76398-013) , label(76398-013) |

Revised: 12/2023

TOM FORD BEAUTY DIST