

**TOM FORD SOLEIL GLOW TONE UP FOUNDATION BROAD SPECTRUM SPF 45-
octinoxate, titanium dioxide, and zinc oxide cream
TOM FORD BEAUTY DIST**

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.

TOM FORD SOLEIL GLOW TONE UP FOUNDATION BROAD SPECTRUM SPF 45

Drug Facts

Active ingredients

Octinoxate 4.0%

Titanium Dioxide 6.1%

Zinc Oxide 3.8%

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 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\aquaeau • dimethicone • octyldodecyl neopentanoate • butyloctyl salicylate • isononyl isononanoate • methyl trimethicone • diethylhexyl succinate • lauryl peg-9 polydimethylsiloxyethyl dimethicone • laureth-4 • cetyl peg/ppg-10/1 dimethicone • butylene glycol • magnesium sulfate • dipentaerythrityl tri-polyhydroxystearate • sigesbeckia orientalis (st. paul's wort) extract • glycerin • lens esculenta (lentil) fruit extract • pyrus malus (apple) fruit extract • thermus thermophilus ferment • algae extract • citrullus vulgaris (watermelon) fruit extract • narcissus tazetta bulb extract • saccharomyces lysate extract • laminaria digitata extract • morinda citrifolia fruit extract • whey protein\lactis protein\proteine du petit-lait • chlorella vulgaris extract • ergothioneine • palmitoyl hexapeptide-12 • polygonum cuspidatum root extract • sapindus mukorossi fruit extract • pearl powder • acetyl hexapeptide-8 • lavandula angustifolia (lavender) oil • dimethicone silylate • tocopheryl acetate • dimethicone/peg-10/15 crosspolymer • sucrose • hydrolyzed wheat protein\pvp crosspolymer • caprylyl glycol • caffeine • glyceryl polymethacrylate • triethoxycaprylylsilane • methicone • dimethicone crosspolymer-3 • sodium hyaluronate • tetrahexyldecyl ascorbate • disteardimonium hectorite • peg-8 • sodium lactate • dipropylene glycol • sodium pca • glycine soja (soybean) protein • artemia extract • caesalpinia spinosa gum • tin oxide • silica • calcium chloride • alumina • disodium edta • linalool • potassium sorbate • phenoxyethanol • [+/- mica • iron oxides (ci 77491) • iron oxides (ci 77492) • iron oxides (ci 77499) • bismuth oxychloride (ci 77163) • titanium dioxide (ci 77891)]

Other information

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

PRINCIPAL DISPLAY PANEL - 12 g Jar Carton

TOM FORD

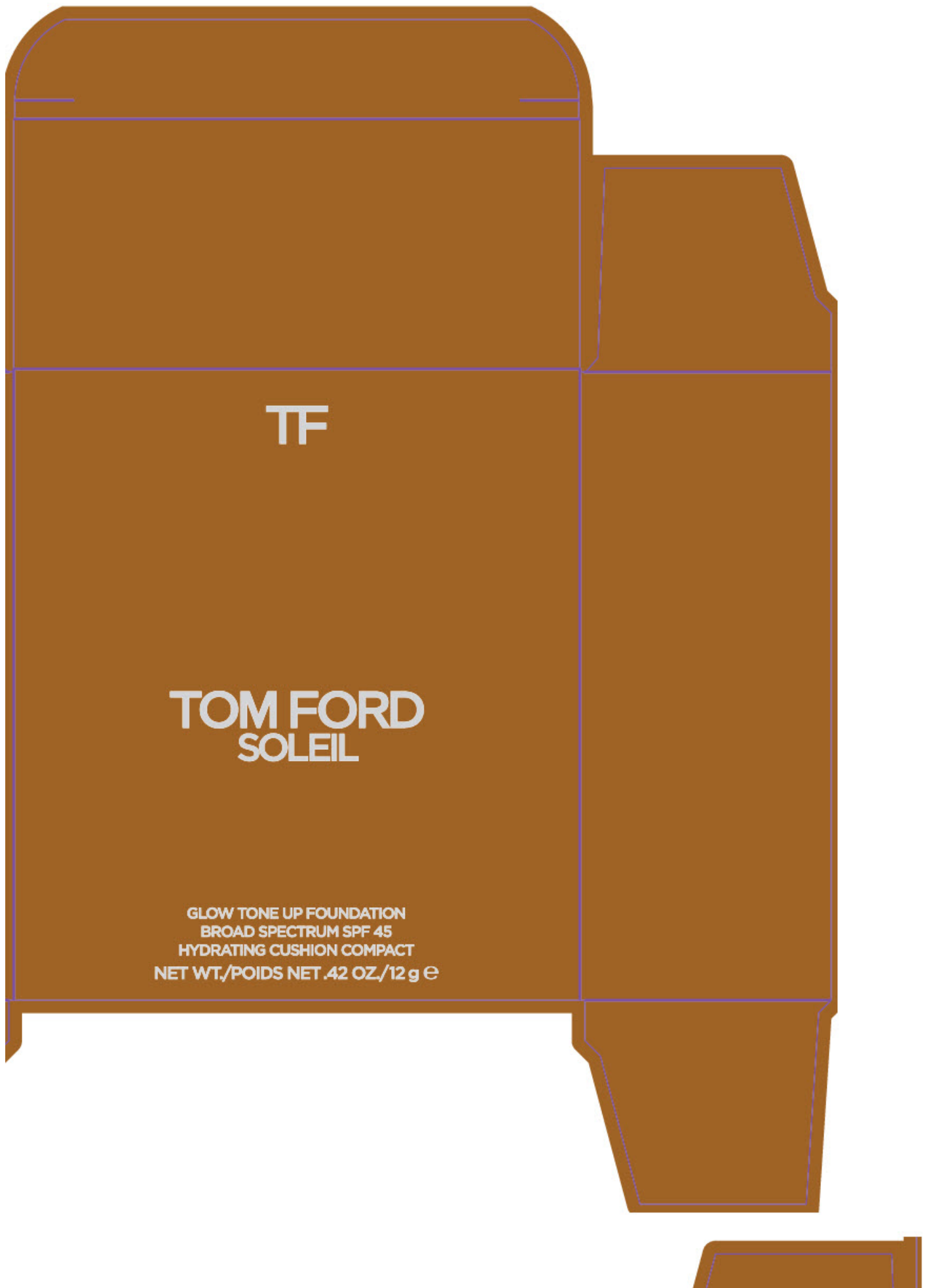
SOLEIL

GLOW TONE UP FOUNDATION

BROAD SPECTRUM SPF 45

HYDRATING CUSHION COMPACT

NET WT. .42 OZ./12 g e



TF

TOM FORD
SOLEIL

GLOW TONE UP FOUNDATION
BROAD SPECTRUM SPF 45
HYDRATING CUSHION COMPACT
NET WT./POIDS NET .42 OZ./12 g e

90557
TP 889



Drug Facts

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Drug Facts [continued]

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Other Information

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TOM FORD BEAUTY, DIST., NEW YORK, NY 10022
WLB LTD., GU32 3DD, UK. MADE IN BELGIUM T6R4



T6R4-01-1112

TOM FORD SOLEIL GLOW TONE UP FOUNDATION BROAD SPECTRUM SPF 45

octinoxate, titanium dioxide, and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76398-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
octinoxate (UNII: 4Y5P7MUD51) (octinoxate - UNII:4Y5P7MUD51)	octinoxate	4 g in 100 g
titanium dioxide (UNII: 15FIX9V2JP) (titanium dioxide - UNII:15FIX9V2JP)	titanium dioxide	6.1 g in 100 g
zinc oxide (UNII: SOI2LOH54Z) (zinc oxide - UNII:SOI2LOH54Z)	zinc oxide	3.8 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
dimethicone (UNII: 92RU3N3Y1O)	
octyldodecyl neopentanoate (UNII: X8725R883T)	
butyloctyl salicylate (UNII: 2EH13UN8D3)	
isononyl isononanoate (UNII: S4V5BS6GCX)	
methyl trimethicone (UNII: S73ZQI0GXM)	
diethylhexyl succinate (UNII: 69W9UMG3P8)	
lauryl peg-9 polydimethylsiloxyethyl dimethicone (UNII: 25G622K2RA)	
laureth-4 (UNII: 6HQ855798J)	
butylene glycol (UNII: 3XUS85K0RA)	
magnesium sulfate, unspecified form (UNII: DE08037SAB)	
dipentaerythrityl tri-polyhydroxystearate (UNII: D21K655H52)	
glycerin (UNII: PDC6A3C0OX)	
lentil (UNII: 6O38V6B52O)	
apple (UNII: B423VGH5S9)	
thermus thermophilus lysate (UNII: 775R692494)	
watermelon (UNII: 231473QB6R)	
whey (UNII: 8617Z5FMF6)	
chlorella vulgaris (UNII: RYQ4R60M02)	
ergothioneine (UNII: BDZ3DQM98W)	
palmitoyl hexapeptide-12 (UNII: HO4ZT5S86C)	
acetyl hexapeptide-8 (UNII: L4EL31FWIL)	
lavender oil (UNII: ZBP1YXW0H8)	
sucrose (UNII: C151H8M554)	
caprylyl glycol (UNII: 00YIU5438U)	
caffeine (UNII: 3G6A5W338E)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
methicone (20 cst) (UNII: 6777U11MKT)	
hyaluronate sodium (UNII: YSE9PPT4TH)	
tetrahexyldecyl ascorbate (UNII: 9LBV3F07AZ)	
disteardimonium hectorite (UNII: X687XDK09L)	
polyethylene glycol 400 (UNII: B697894SGQ)	
sodium lactate (UNII: TU7HW0W0QT)	

dipropylene glycol (UNII: E107L85C40)
sodium pyrrolidone carboxylate (UNII: 469OTG57A2)
soybean (UNII: L7HT8F1ZOD)
caesalpinia spinosa resin (UNII: WL3883U2PO)
stannic oxide (UNII: KM7N50LOS6)
silicon dioxide (UNII: ETJ7Z6XBU4)
calcium chloride (UNII: M4I0D6VV5M)
aluminum oxide (UNII: LM26O6933)
edetate disodium anhydrous (UNII: 8NLQ36F6MM)
linalool, (+/-)- (UNII: D81QY6I88E)
potassium sorbate (UNII: 1VPU26JZZ4)
phenoxyethanol (UNII: HIE492ZZ3T)
mica (UNII: V8A1AW0880)
ferric oxide red (UNII: 1K09F3G675)
ferric oxide yellow (UNII: EX438O2MRT)
ferrosoferric oxide (UNII: XM0M87F357)
bismuth oxychloride (UNII: 4ZR792I587)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76398-007-01	1 in 1 CARTON	02/10/2019	
1		12 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	02/10/2019	

Labeler - TOM FORD BEAUTY DIST (005914387)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(76398-007) , REPACK(76398-007)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(76398-007)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(76398-007)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(76398-007)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(76398-007)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(76398-007) , REPACK(76398-007)

Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(76398-007) , REPACK(76398-007)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(76398-007)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(76398-007)

Establishment

Name	Address	ID/FEI	Business Operations
COSMAX INC.		689049693	MANUFACTURE(76398-007)