

TOM FORD FLAWLESS GLOW FOUNDATION BROAD SPECTRUM SPF 30- octinoxate, titanium dioxide, and zinc oxide lotion
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 FLAWLESS GLOW FOUNDATION BROAD SPECTRUM SPF 30

Drug Facts

Active Ingredients	Purpose
Octinoxate 5.0%	Sunscreen
Titanium Dioxide 3.1%	Sunscreen
Zinc Oxide 2.2%	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 • methyl trimethicone • phenyl trimethicone • silica • butyloctyl salicylate • dimethicone • neopentyl glycol diheptanoate • c12-15 alkyl benzoate • butylene glycol • lauryl peg-9 polydimethylsiloxylethyl dimethicone • ethylhexyl palmitate • glycerin • trimethylsiloxysilicate/dimethiconol crosspolymer • polysilicone-11 • sapindus mukorossi fruit extract • caffeine • lavandula angustifolia (lavender) oil • thermus thermophilus ferment • caesalpinia spinosa gum • morinda citrifolia fruit extract • sodium hyaluronate • dimethicone/peg-10/15 crosspolymer •

peg-10 dimethicone • sodium lactate • sodium pca • polyglutamic acid • lecithin • litchi chinensis seed extract • laminaria saccharina extract • methicone • triethyl citrate • tocopheryl acetate • zinc stearate • caprylyl glycol • trimethylsiloxysilicate • disteardimonium hectorite • laureth-7 • citrullus vulgaris (watermelon) fruit extract • lens esculenta (lentil) fruit extract • glycine soja (soybean) protein • pyrus malus (apple) fruit extract • tetrahexyldecyl ascorbate • triethoxycaprylylsilane • hexylene glycol • xanthan gum • calcium chloride • sodium chloride • dipropylene glycol • dextrin • dimethicone silylate • magnesium aluminum silicate • linalool • silica dimethyl silylate • sodium citrate • disodium edta • bht • potassium sorbate • sodium benzoate • sodium dehydroacetate • phenoxyethanol • [+/- mica • titanium dioxide (ci 77891) • iron oxides (ci 77491) • iron oxides (ci 77492) • iron oxides (ci 77499)]
<iln46394>

Other Information

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

PRINCIPAL DISPLAY PANEL - 30 ml Bottle Carton

TOM FORD
SOLEIL

FLAWLESS GLOW FOUNDATION
BROAD SPECTRUM SPF 30

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

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TP 876
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FLAWLESS GLOW FOUNDATION
BROAD SPECTRUM SPF 30

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TOM FORD BEAUTY, DIST.
NEW YORK, NY 10022
WLB LTD, GU32 3DD, UK
WLBLS NV, OREVEL, BE-2260
MADE IN BELGIUM T7NX

Drug Facts [continued]
benzoate • butylene glycol • lauryl peg-9 polydimethylsiloxyethyl dimethicone • ethylhexyl palmitate • glycerin • trimethylsiloxy silicate/ dimethiconol crosspolymer • polysilicone-11 • sapindus mukorossi fruit extract • caffeine • lavandula angustifolia (lavender) oil • thermus thermophilus ferment • caesalpinia spinosa gum • morinda citrifolia fruit extract • sodium hyaluronate • dimethicone/peg-10/15 crosspolymer • peg-10 dimethicone • sodium lactate • sodium pca • polyglutamic acid • lecithin • litchi chinensis seed extract • laminaria saccharina extract • methicone • triethyl citrate • tocopheryl acetate • zinc stearate • caprylyl glycol • trimethylsiloxy silicate • disteardimonium hectorite • laureth-7 • citrullus vulgaris (watermelon) fruit extract • lens esculenta (lentil) fruit extract • glycine soja (soybean) protein • pyrus malus (apple) fruit extract • tetrahydroxydecyl ascorbate • triethoxycaprylylsilane • hexylene glycol • xanthan gum • calcium chloride • sodium chloride • dipropylene glycol • dextrin • dimethicone silylate • magnesium aluminum silicate • linalool • silica dimethyl silylate • sodium citrate • disodium edta • bht • potassium sorbate • sodium benzoate • sodium dehydroacetate • phenoxyethanol • [+/- mica • titanium dioxide (ci 77891) • iron oxides (ci 77491) • iron oxides (ci 77492) • iron oxides (ci 77499)] <n46394>

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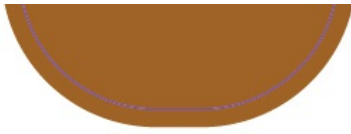
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TOM FORD
SOLEIL

FLAWLESS GLOW FOUNDATION
BROAD SPECTRUM SPF 30
1 FL. OZ./OZ, LIQ./30 ml e

90527 7012

T7NX-01-1112



TOM FORD FLAWLESS GLOW FOUNDATION BROAD SPECTRUM SPF 30

octinoxate, titanium dioxide, and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76398-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
octinoxate (UNII: 4Y5P7MUD51) (octinoxate - UNII:4Y5P7MUD51)	octinoxate	0.056 g in 100 mL
titanium dioxide (UNII: 15FIX9V2JP) (titanium dioxide - UNII:15FIX9V2JP)	titanium dioxide	0.035 g in 100 mL
zinc oxide (UNII: SOI2LOH54Z) (zinc oxide - UNII:SOI2LOH54Z)	zinc oxide	0.024 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
methyl trimethicone (UNII: S73ZQI0GXM)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
butyloctyl salicylate (UNII: 2EH13UN8D3)	
dimethicone (UNII: 92RU3N3Y1O)	
neopentyl glycol diheptanoate (UNII: 5LKW3C543X)	
alkyl (c12-15) benzoate (UNII: A9EJ3J61HQ)	
butylene glycol (UNII: 3XUS85K0RA)	
lauryl peg-9 polydimethylsiloxyethyl dimethicone (UNII: 25G622K2RA)	
ethylhexyl palmitate (UNII: 2865993309)	
glycerin (UNII: PDC6A3C0OX)	
caffeine (UNII: 3G6A5W338E)	
lavender oil (UNII: ZBP1YXW0H8)	
thermus thermophilus lysate (UNII: 775R692494)	
caesalpinia spinosa resin (UNII: WL3883U2PO)	
hyaluronate sodium (UNII: YSE9PPT4TH)	
peg-10 dimethicone (600 CST) (UNII: 8PR7V1SVM0)	
sodium lactate (UNII: TU7HW0W0QT)	
sodium pyrrolidone carboxylate (UNII: 469OTG57A2)	
methicone (20 cst) (UNII: 6777U11MKT)	
triethyl citrate (UNII: 8Z96QXD6UM)	
zinc stearate (UNII: H92E6QA4FV)	
caprylyl glycol (UNII: 00YIU5438U)	
disteardimonium hectorite (UNII: X687XDK09L)	
laureth-7 (UNII: Z95S6G8201)	

watermelon (UNII: 231473QB6R)
lentil (UNII: 6O38V6B52O)
soybean (UNII: L7HT8F1ZOD)
apple (UNII: B423VGH5S9)
tetrahexyldecyl ascorbate (UNII: 9LBV3F07AZ)
triethoxycaprylylsilane (UNII: LDC331P08E)
hexylene glycol (UNII: KEH0A3F75J)
xanthan gum (UNII: TTV12P4NEE)
calcium chloride (UNII: M4I0D6VV5M)
sodium chloride (UNII: 451W47IQ8X)
dipropylene glycol (UNII: E107L85C40)
magnesium aluminum silicate (UNII: 6M3P64V0NC)
linalool, (+/-)- (UNII: D81QY6I88E)
silica dimethyl silylate (UNII: EU2PSP0G0W)
sodium citrate, unspecified form (UNII: 1Q73Q2JULR)
edetate disodium anhydrous (UNII: 8NLQ36F6MM)
butylated hydroxytoluene (UNII: 1P9D0Z171K)
potassium sorbate (UNII: 1VPU26JZZ4)
sodium benzoate (UNII: OJ245FE5EU)
sodium dehydroacetate (UNII: 8W46YN971G)
phenoxyethanol (UNII: HIE492ZZ3T)
mica (UNII: V8A1AW0880)
ferric oxide red (UNII: 1K09F3G675)
ferric oxide yellow (UNII: EX438O2MRT)
ferrosoferric oxide (UNII: XM0M87F357)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76398-008-01	1 in 1 CARTON	02/15/2019	
1		30 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 NOT FINAL	part352	02/15/2019	

Labeler - TOM FORD BEAUTY DIST (005914387)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(76398-008) , REPACK(76398-008)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(76398-008)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(76398-008)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370 151326	MANUFACTURE(76398-008)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(76398-008)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(76398-008) , REPACK(76398-008)

Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(76398-008) , REPACK(76398-008)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(76398-008)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(76398-008)