

**TOM FORD SOLEIL GLOW TINTED MOISTURIZER BROAD SPECTRUM SPF 15-
octinoxate and titanium dioxide liquid
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 TINTED MOISTURIZER BROAD SPECTRUM SPF 15

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
Octinoxate 7.5%	Sunscreen
Titanium Dioxide 2.9%	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 • phenyl trimethicone • butylene glycol • pentaerythrityl tetraethylhexanoate • simmondsia chinensis (jojoba) seed oil • petrolatum • biosaccharide gum - 1 • steareth-21 • glyceryl stearate • tocopheryl acetate • sodium hyaluronate • ethylhexylglycerin • peg-12 dimethicone • isohexadecane • magnesium aluminum silicate • xanthan gum • lecithin • aluminum hydroxide • citric acid • steareth-2 • polymethyl methacrylate • cetyl alcohol • potassium stearate • acrylamide/sodium acryloyldimethyltaurate copolymer • polysorbate 80 • caprylyl glycol • lavandula angustifolia (lavender) oil • linalool • tocopherol • phenoxyethanol • bht • sorbic acid • disodium edta • [+/-titanium

dioxide (ci 77891) • iron oxides (ci 77491) • iron oxides (ci 77492) • iron oxides (ci 77499)]
<iln47202>

Other Information

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

PRINCIPAL DISPLAY PANEL - 50 ml Tube Carton

TOM FORD
SOLEIL

GLOW TINTED MOISTURIZER
BROAD SPECTRUM SPF 15

1.7 FL. OZ./OZ. LIQ./50 ml e

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TP 1215

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TOM FORD BEAUTY, DIST.
NEW YORK, NY 10022
WLB LTD, GU32 3DD, UK
WLB NV, OEVEL, BE-2260
MADE IN BELGIUM T8C1

TF

TOM FORD
SOLEIL

Drug Facts [continued]

isohexadecane • magnesium aluminum silicate • xanthan gum • lecithin • aluminum hydroxide • citric acid • steareth-2 • polymethyl methacrylate • cetyl alcohol • potassium stearate • acrylamide/sodium acryloyldimethyltaurate copolymer • polysorbate 80 • caprylyl glycol • lavandula angustifolia (lavender) oil • linalool • tocopherol • phenoxyethanol • bht • sorbic acid • disodium edta • [+/- titanium dioxide (ci 77891) • iron oxides (ci 77491) • iron oxides (ci 77492) • iron oxides (ci 77499)] <ln47202>

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GLOW TINTED MOISTURIZER
BROAD SPECTRUM SPF 15
1.7 FL. OZ./OZ. LIQ./50 ml e

90824
4067

TOM FORD SOLEIL GLOW TINTED MOISTURIZER BROAD SPECTRUM SPF 15

octinoxate and titanium dioxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76398-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	78 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
butylene glycol (UNII: 3XUS85K0RA)	
pentaerythrityl tetraethylhexanoate (UNII: XJ7052W897)	
jojoba oil (UNII: 724GKU717M)	
petrolatum (UNII: 4T6H12BN9U)	
biosaccharide gum-1 (UNII: BB4PU4V09H)	
steareth-21 (UNII: 53J3F32P58)	
glyceryl monostearate (UNII: 230OU9XXE4)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
hyaluronate sodium (UNII: YSE9PPT4TH)	
ethylhexylglycerin (UNII: 147D247K3P)	
peg-12 dimethicone (300 cst) (UNII: ZEL54N6W95)	
isohexadecane (UNII: 918X1OUF1E)	
magnesium aluminum silicate (UNII: 6M3P64V0NC)	
xanthan gum (UNII: TTV12P4NEE)	
aluminum hydroxide (UNII: 5QB0T2IUN0)	
citric acid monohydrate (UNII: 2968PHW8QP)	
steareth-2 (UNII: V56DFE46J5)	
poly(methyl methacrylate; 450000 mw) (UNII: Z47NNT4J11)	
cetyl alcohol (UNII: 936JST6JCN)	
potassium stearate (UNII: 17V812XK50)	
polysorbate 80 (UNII: 6OZP39ZG8H)	

caprylyl glycol (UNII: 00 YIU5438U)	
lavender oil (UNII: ZBP1YXW0H8)	
linalool, (+/-)- (UNII: D8 1QY6I88E)	
tocopherol (UNII: R0 ZB2556P8)	
phenoxyethanol (UNII: HIE492ZZ3T)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
sorbic acid (UNII: X045WJ989B)	
edetate disodium anhydrous (UNII: 8NLQ36F6MM)	
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:76398-012-01	1 in 1 CARTON	02/21/2020	
1		50 mL in 1 TUBE; 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	02/21/2020	

Labeler - TOM FORD BEAUTY DIST (005914387)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(76398-012) , REPACK(76398-012)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(76398-012)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(76398-012)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(76398-012)

Establishment			
Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(76398-012)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(76398-012) , REPACK(76398-012)

Establishment			
Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(76398-012) , REPACK(76398-012)

Establishment			
Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(76398-012)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(76398-012)

Revised: 2/2020

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