

TOM FORD SOLEIL TINTED MOISTURIZER BROAD SPECTRUM SPF 30- octinoxate, octisalate, and titanium dioxide 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 TINTED MOISTURIZER BROAD SPECTRUM SPF 30

Drug Facts

Active Ingredients	Purpose
Octinoxate 7.5%	Sunscreen
Octisalate 2.0%	Sunscreen
Titanium Dioxide 5.3%	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 • butylene glycol • octyldodecyl neopentanoate • cetyl alcohol • laureth-4 • ascorbyl glucoside • neopentyl glycol diheptanoate • polyethylene • morinda citrifolia fruit extract • sapindus mukorossi fruit extract • lavandula angustifolia (lavender) oil • cucumis sativus (cucumber) fruit extract • PEG-100 stearate • scutellaria baicalensis root extract • helianthus annuus (sunflower) seedcake • morus nigra (mulberry) root extract • hydrogenated lecithin • corallina officinalis extract • gelidium cartilagineum extract • vitis vinifera (grape) fruit extract • saccharomyces lysate extract • laminaria

saccharina extract • laminaria digitata extract • sigesbeckia orientalis (st. paul's wort) extract • acetyl hexapeptide-8 • sucrose • glycerin • glycyrrhetic acid • caffeine • propylene glycol diethylhexanoate • lecithin • isohexadecane • polyglyceryl-3 beeswax • whey protein/lactis protein/proteine du petit-lait • dimethoxytolyl propylresorcinol • acetyl glucosamine • PVP/hexadecene copolymer • tourmaline • yeast polysaccharides • caprylyl glycol • yeast extract/faex/extrait de levure • isostearic acid • propylene glycol dicaprate • hordeum vulgare (barley) extract/extrait d'orge • stearic acid • tromethamine • acrylamide/sodium acryloyldimethyltaurate copolymer • galactoarabinan • nylon-12 • synthetic fluorophlogopite • tocopheryl linoleate/oleate • sodium hyaluronate • boron nitride • xanthan gum • polysorbate 80 • silica • aluminum hydroxide • caesalpinia spinosa gum • tin oxide • disodium EDTA • BHT • linalool • phenoxyethanol • [+/- mica • titanium dioxide (CI 77891) • iron oxides (CI 77491) • iron oxides (CI 77492) • iron oxides (CI 77499)] <ILN43839>

Other Information

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

PRINCIPAL DISPLAY PANEL - 30 ml Bottle Carton

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TOM FORD

SOLEIL TINTED MOISTURIZER

BROAD SPECTRUM SPF 30

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

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TP 626
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TOM FORD BEAUTY, DIST. NEW YORK, NY 10022
W.L.B.LTD., G.U.32, 3DQ.LK. MADE IN BELGIUM. TSJF



Drug Facts [continued]

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Drug Facts [continued]

tocopheryl linoleate/oleate • sodium hyaluronate • boron nitride • xanthan gum • polysorbate 80 • silica • aluminum hydroxide • caesalpinia spinosa gum • tin oxide • disodium EDTA • BHT • linalool • phenoxyethanol • [+/- mica • titanium dioxide (CI 77891) • iron oxides (CI 77491) • iron oxides (CI 77492) • iron oxides (CI 77499)] <ILN43839>

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SOLEIL TINTED MOISTURIZER
BROAD SPECTRUM SPF 30
1 FL. OZ./OZ. LIQ./30 ml e

TSJF-01-111



2053 3021

TOM FORD SOLEIL TINTED MOISTURIZER BROAD SPECTRUM SPF 30

octinoxate, octisalate, and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76398-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0825 g in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	0.022 g in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	0.0583 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
LAURETH-4 (UNII: 6HQ855798J)	
ASCORBYL GLUCOSIDE (UNII: 2V52R0NHXW)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
NONI FRUIT (UNII: 7829X3G2X5)	
SAPINDUS MUKOROSSII FRUIT (UNII: 66H9NW427Y)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
CUCUMBER (UNII: YY7C30VXJT)	
PEG-100 STEARATE (UNII: YD01N1999R)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
HELIANTHUS ANNUUS SEEDCAKE (UNII: 482WYF7XLC)	
MORUS NIGRA ROOT (UNII: 033456LFG1)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
CORALLINA OFFICINALIS (UNII: 4004498D06)	
GELIDIUM CARTILAGINEUM (UNII: 37LBZ0E1UE)	
WINE GRAPE (UNII: 3GOV20705G)	
SACCHAROMYCES LYSATE (UNII: R85W246Z1C)	
SACCHARINA LATISSIMA (UNII: 68CMP2MB55)	
LAMINARIA DIGITATA (UNII: 15E7C67EE8)	
ACETYL HEXAPEPTIDE-8 (UNII: L4EL31FWIL)	
SUCROSE (UNII: C151H8M554)	
GLYCERIN (UNII: PDC6A3C0OX)	
ENOXOLONE (UNII: P540XA09DR)	
CAFFEINE (UNII: 3G6A5W338E)	
PROPYLENE GLYCOL DIETHYLHEXANOATE (UNII: 8D8I9Z0F1Z)	
ISOHEXADECANE (UNII: 918X10UF1E)	
DIMETHOXYTOLYL PROPYLRESORCINOL (UNII: 4OD5GIH1UK)	

N-ACETYLGLUCOSAMINE (UNII: V956696549)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
ISOSTEARIC ACID (UNII: X33R8U0062)
PROPYLENE GLYCOL DICAPRATE (UNII: U783H9JHWY)
STEARIC ACID (UNII: 4ELV7Z65AP)
TROMETHAMINE (UNII: 023C2WHX2V)
GALACTOARABINAN (UNII: SL4SX1O487)
NYLON-12 (UNII: 446U8J075B)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
BORON NITRIDE (UNII: 2U4T60A6YD)
XANTHAN GUM (UNII: TTV12P4NEE)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
CAESALPINIA SPINOSA RESIN (UNII: WL3883U2PO)
STANNIC OXIDE (UNII: KM7N50LOS6)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76398-005-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/01/2017	

Labeler - TOMFORD BEAUTY DIST (005914387)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(76398-005) , REPACK(76398-005)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(76398-005)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(76398-005)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(76398-005)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(76398-005)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(76398-005) , REPACK(76398-005)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC LLC		959338336	MANUFACTURE(76398-005)

Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(76398-005) , REPACK(76398-005)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(76398-005)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(76398-005)