

**TOM FORD FACE PROTECT BROAD SPECTRUM SPF 50- avobenzone, homosalate, octisalate, octocrylene, and oxybenzone 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.*

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**TOM FORD FACE PROTECT BROAD SPECTRUM SPF 50**

***Drug Facts***

<b><i>Active Ingredients</i></b>	<b><i>Purpose</i></b>
Avobenzone 3.0%	Sunscreen
Homosalate 5.0%	Sunscreen
Octisalate 5.0%	Sunscreen
Octocrylene 2.8%	Sunscreen
Oxybenzone 3.0%	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

**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 • butyloctyl salicylate • neopentyl glycol diheptanoate • aleurites moluccana (kukui) seed oil • lauryl PEG-9 polydimethylsiloxylethyl dimethicone • PEG-100 stearate • butylene glycol • glyceryl stearate • dipentaerythryl tri-polyhydroxystearate • potassium cetyl

phosphate • algae extract • laminaria ochroleuca extract • scutellaria baicalensis root extract • glycyrrhetic acid • caffeine • caprylic/capric triglyceride • cholesterol • sorbitol • yeast polysaccharides • ethylhexylglycerin • sodium hyaluronate • cetyl alcohol • caprylyl glycol • vp/eicosene copolymer • saccharide isomerate • tetrahexyldecyl ascorbate • tocopheryl acetate • ammonium acryloyldimethyltaurate/vp copolymer • stearic acid • dehydroxanthan gum • fragrance (parfum) • sodium dehydroacetate • sodium hydroxide • citric acid • silica • disodium EDTA • BHT • phenoxyethanol • mica • titanium dioxide (CI 77891) <ILN42872>

### **Other Information**

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

### **PRINCIPAL DISPLAY PANEL - 30 ml Tube Carton**

**TF**

**TOM FORD**

**FACE PROTECT**

**BROAD SPECTRUM SPF 50**

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

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**FACE PROTECT**  
**BROAD SPECTRUM SPF 50**  
APPLY AS THE LAST STEP OF MORNING  
REGIMEN, WEAR ALONE OR FOLLOW  
WITH FOUNDATION.

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TOM FORD BEAUTY, DIST.  
NEW YORK, NY 10022  
W.B.LTD. GU32 3DD, UK  
MADE IN U.S.A. T4JC



**Drug Facts [continued]**

- wear long-sleeved shirts, pants hats and sunglasses
- children under 6 months of age: ask a doctor

**Inactive Ingredients**

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TOM FORD

FACE PROTECT  
BROAD SPECTRUM SPF 50  
1 FL. OZ./OZ. LIQ./30 ml e

T4JC-01-1111

# TOM FORD FACE PROTECT BROAD SPECTRUM SPF 50

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76398-004
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>avobenzone</b> (UNII: G63QQF2NOX) (avobenzone - UNII:G63QQF2NOX)	avobenzone	0.03105 g in 1 mL
<b>homosalate</b> (UNII: V06SV4M95S) (homosalate - UNII:V06SV4M95S)	homosalate	0.05175 g in 1 mL
<b>octisalate</b> (UNII: 4X49Y0596W) (octisalate - UNII:4X49Y0596W)	octisalate	0.05175 g in 1 mL
<b>octocrylene</b> (UNII: 5A68WGF6WM) (octocrylene - UNII:5A68WGF6WM)	octocrylene	0.029898 g in 1 mL
<b>oxybenzone</b> (UNII: 95OOS7VE0Y) (oxybenzone - UNII:95OOS7VE0Y)	oxybenzone	0.03105 g in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>water</b> (UNII: 059QF0K00R)	
<b>methyl trimethicone</b> (UNII: S73ZQI0GXM)	
<b>butyloctyl salicylate</b> (UNII: 2EH13UN8D3)	
<b>neopentyl glycol diheptanoate</b> (UNII: 5LKW3C543X)	
<b>kukui nut oil</b> (UNII: TP11QR7B8R)	
<b>lauryl PEG-9 polydimethylsiloxyethyl dimethicone</b> (UNII: 25G622K2RA)	
<b>PEG-100 stearate</b> (UNII: YD01N1999R)	
<b>butylene glycol</b> (UNII: 3XUS85K0RA)	
<b>glyceryl monostearate</b> (UNII: 230OU9XXE4)	
<b>dipentaerythrityl tri-polyhydroxystearate</b> (UNII: D21K655H52)	
<b>potassium cetyl phosphate</b> (UNII: 03KCY6P7UT)	
<b>laminaria ochroleuca</b> (UNII: 4R2124HE76)	
<b>scutellaria baicalensis root</b> (UNII: 7J95K7ID2S)	
<b>enoxolone</b> (UNII: P540XA09DR)	
<b>caffeine</b> (UNII: 3G6A5W338E)	
<b>medium-chain triglycerides</b> (UNII: C9H2L21V7U)	
<b>cholesterol</b> (UNII: 97C5T2UQ7J)	
<b>sorbitol</b> (UNII: 506T60A25R)	
<b>ethylhexylglycerin</b> (UNII: 147D247K3P)	
<b>hyaluronate sodium</b> (UNII: YSE9PPT4TH)	
<b>cetyl alcohol</b> (UNII: 936JST6JCN)	
<b>caprylyl glycol</b> (UNII: 00YIU5438U)	
<b>saccharide isomerate</b> (UNII: W8K377W98I)	
<b>tetrahexyldecyl ascorbate</b> (UNII: 9LBV3F07AZ)	
<b>.alpha.-tocopherol acetate</b> (UNII: 9E8X80D2L0)	
<b>ammonium acryloyldimethyltaurate/vp copolymer</b> (UNII: W59H9296ZG)	
<b>stearic acid</b> (UNII: 4ELV7Z65AP)	
<b>dehydroxanthan gum</b> (UNII: 63ZP7I1BQO)	
<b>sodium dehydroacetate</b> (UNII: 8W46YN971G)	

sodium hydroxide (UNII: 55X04QC32I)	
citric acid monohydrate (UNII: 2968PHW8QP)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
edetate disodium anhydrous (UNII: 8NLQ36F6MM)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
phenoxyethanol (UNII: HIE492ZZ3T)	
mica (UNII: V8A1AW0880)	
titanium dioxide (UNII: 15FIX9V2JP)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76398-004-01	1 in 1 CARTON	01/01/2017	
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	01/01/2017	

**Labeler** - TOMFORD BEAUTY DIST (005914387)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(76398-004) , REPACK(76398-004)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(76398-004)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(76398-004)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(76398-004)

Establishment			
Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(76398-004)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(76398-004) , REPACK(76398-004)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
PADC 1		949264774	RELABEL(76398-004) , REPACK(76398-004)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(76398-004)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(76398-004)

Revised: 11/2018

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