

**ILLUMINATING PROTECTIVE PRIMER SPF 12- octinoxate, homosalate 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.*

-----  
ACTIVE INGREDIENTS: OCTINOXATE 7.50% [] HOMOSALATE 5.00%

INGREDIENTS: WATER\AQUA\EAU [] PEG-4 DIHEPTANOATE [] GLYCERIN [] BIS-DIGLYCERYL POLYACYLADIPATE-2 [] BUTYROSPERMUM PARKII (SHEA BUTTER) [] PHENYL TRIMETHICONE [] POLYETHYLENE [] CETEARYL ALCOHOL [] DIMETHICONE [] TOCOPHERYL ACETATE [] CETYL ALCOHOL [] GLYCERYL STEARATE [] EPILOBIUM ANGUSTIFOLIUM EXTRACT [] VANILLA PLANIFOLIA FRUIT EXTRACT [] DIPTERYX ODORATA SEED EXTRACT [] SAPINDUS MUKUROSSI FRUIT EXTRACT [] MORINDA CITRIFOLIA FRUIT EXTRACT [] COCOS NUCIFERA (COCONUT) OIL [] POGOSTEMON CABLIN (PATCHOULI) OIL [] CANANGA ODORATA FLOWER OIL [] AMYRIS BALSAMIFERA BARK OIL [] VETIVERIA ZIZANOIDES ROOT OIL [] CITRUS AURANTIUM BERGAMIA (BERGAMOT) FRUIT OIL [] OENOTHERA BIENNIS (EVENING PRIMROSE) OIL [] LECITHIN [] CAFFEINE [] CAESALPINIA SPINOSA GUM [] PROPYLENE GLYCOL LAURATE [] SQUALANE [] SORBITAN STEARATE [] PEG-40 STEARATE [] HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER [] ETHYLHEXYLGLYCERIN [] BUTYLENE GLYCOL [] DICETYL PHOSPHATE [] CETETH-10 PHOSPHATE [] XANTHAN GUM [] POLYSORBATE 60 [] PROPYLENE GLYCOL STEARATE [] SODIUM HYALURONATE [] SORBITAN LAURATE [] POTASSIUM SORBATE [] POLYSORBATE 20 [] CITRIC ACID [] TIN OXIDE [] TETRASODIUM EDTA [] PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE [] LINALOOL [] LIMONENE [] CHLORPHENESIN [] PHENOXYETHANOL [] [+/- TITANIUM DIOXIDE (CI 77891) [] MICA]

WARNING: KEEP OUT OF EYES. STOP USE IF IRRITATION OCCURS. KEEP OUT OF REACH OF CHILDREN.

PRINCIPAL DISPLAY PANEL:

TF

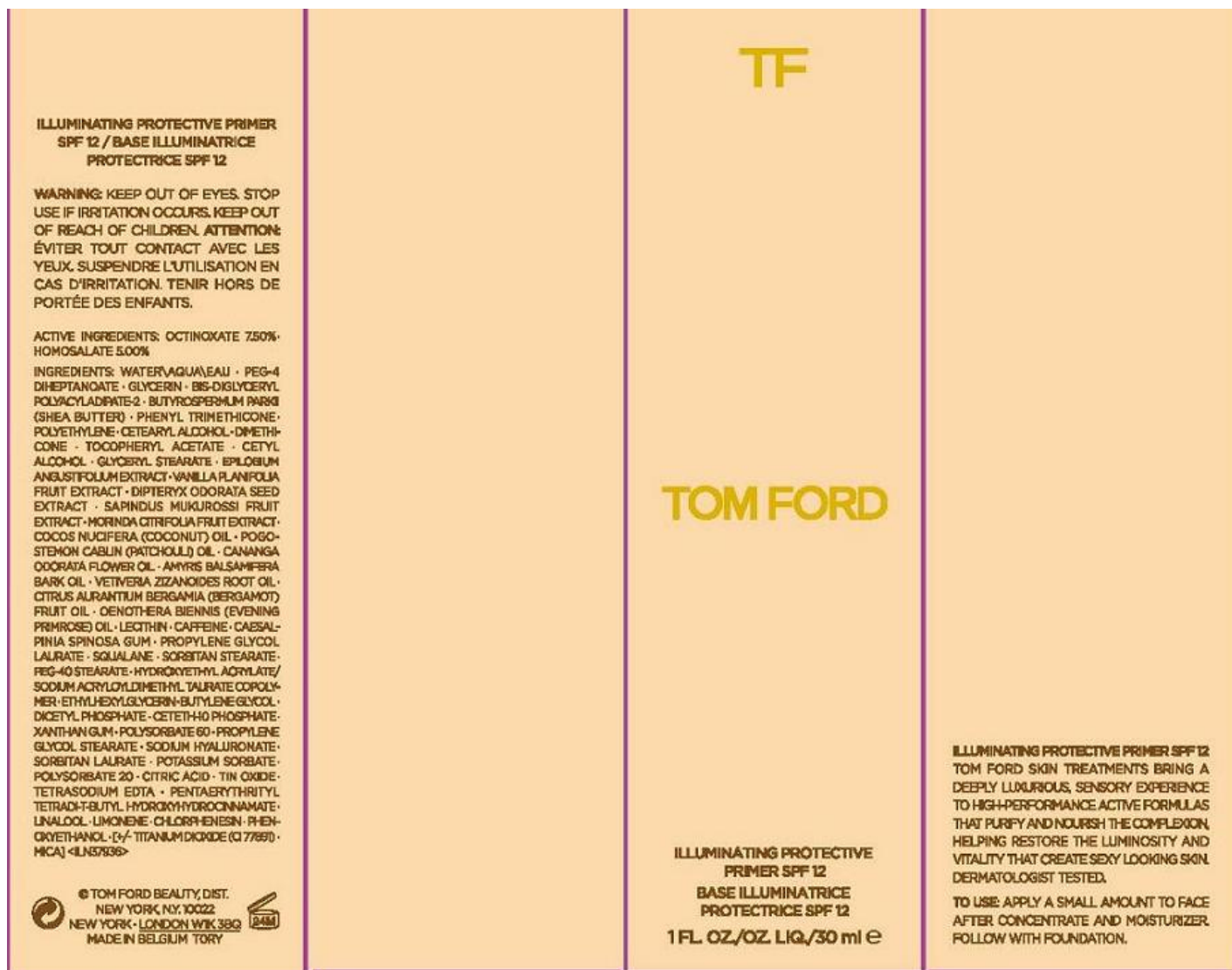
TOM FORD

ILLUMINATING PROTECTIVE PRIMER SPF 12

1 OZ./FL.OZ./30 ML

TOM FORD BEAUTY DIST

NEW YORK, NY 10022



## ILLUMINATING PROTECTIVE PRIMER SPF 12

octinoxate, homosalate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76398-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mL in 100 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5.0 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

SHEA BUTTER (UNII: K49155WL9Y)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
EPILOBIUM ANGUSTIFOLIUM LEAF (UNII: 7NV86426N2)	
VANILLA (UNII: Q74T35078H)	
DIPTERYX ODORATA SEED (UNII: D43A5L1U6L)	
SAPINDUS MUKOROSSIFRUIT (UNII: 66H9NW427Y)	
COCONUT OIL (UNII: Q9L0O73W7L)	
PATCHOULI OIL (UNII: F3IN55X5PO)	
CANANGA OIL (UNII: 8YOY78GNNX)	
AMYRIS BALSAMIFERA OIL (UNII: I1BJ961J2E)	
VETIVER OIL (UNII: 9M9P32M01L)	
BERGAMOT OIL (UNII: 39W1PKE3J1)	
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CAFFEINE (UNII: 3G6A5W338E)	
CAESALPINIA SPINOSA RESIN (UNII: WL3883U2PO)	
PROPYLENE GLYCOL LAURATES (UNII: 40KT317HGP)	
SQUALANE (UNII: GW89575KF9)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SORBITAN MONOLAURATE (UNII: 6W9PS8B71J)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
EDETATE SODIUM (UNII: MP1J8420LU)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MICA (UNII: V8A1AW0880)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76398-001-01	1 in 1 CARTON		
1	NDC:76398-001-02	30 mL in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/01/2009	

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

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		205952385	manufacture

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	manufacture

## Establishment

Name	Address	ID/FEI	Business Operations
Len-Ron Manufacturing Division of Aramis Inc.		809771152	manufacture

## Establishment

Name	Address	ID/FEI	Business Operations
Aramis Inc.		042918826	manufacture

## Establishment

Name	Address	ID/FEI	Business Operations
Northtec Bristol		949264774	manufacture, relabel, repack

## Establishment

Name	Address	ID/FEI	Business Operations
Northtec Keystone		618107429	manufacture, relabel, repack

## Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2		828534516	manufacture, relabel, repack

## Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics, Ltd.		255175580	manufacture

## Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics, Ltd		253616536	manufacture

## Establishment

Name	Address	ID/FEI	Business Operations
------	---------	--------	---------------------

Estee Lauder Cosmetics Distribution Center		208579636	repack, relabel
--	--	-----------	-----------------

### Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Kabushiki Kaisha		712808195	relabel, repack

### Establishment

Name	Address	ID/FEI	Business Operations
Whitman Laboratories Ltd.		216866277	manufacture

### Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	manufacture

Revised: 10/2011

TOM FORD BEAUTY DIST