

ELF TINTED MOISTURIZER SPF 15 - oxybenzone cream
Hangzhou Facecare Cosmetics Co., Ltd.

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.

Drug Fact

Active Ingredient:

Benzophenone-3: 5.0%

Octyl Methoxycinnamate: 7.0%

Purpose:

Sunscreen

Uses:

- Hydrates, softens and smooths skin
- Instant natural radiant glow
- Helps protect against sun and skin aging

Warning:

For external use only

When Using This Product:

Do not get into eyes

Stop Use And Ask A Doctor If:

Rash or irritation develops and lasts

Keep Out of Reach Of Children:

If swallowed get medical help or contact a Poison Control Center immediately

Directions:

Massage a pearl-sized amount into skin and neck daily.

Other Information:

Store at room temperature 15-30C (59-86F)

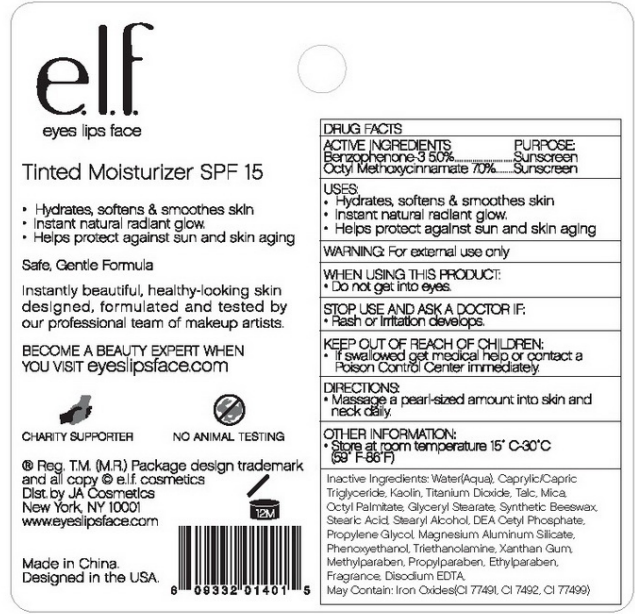
Inactive Ingredient:

Water, Caprylic/Capric Triglyceride, Kaolin, Titanium Dioxide, Talc, Mica, Octyl Palmitate, Glyceryl Stearate, Synthetic Beeswax, Stearic Acid, Stearyl Alcohol, DEA-Cetyl Phosphate, Propylene Glycol, Magnesium Aluminum Silicate, Phenoxyethanol, Triethanolamine, Xanthan Gum, Fragrance, Methylparaben, Propylparaben, Ethylparaben, Disodium EDTA.

May contain:

Iron Oxides (CI 77491, CI 77492, CI 77499)

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ELF TINTED MOISTURIZER SPF 15

oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52664-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MICA (UNII: V8A1AW0880)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
KAOLIN (UNII: 24H4NWX5CO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
TALC (UNII: 7SEV7J4R1U)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
WHITE WAX (UNII: 7G1J5DA97F)	

STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
DIETHANOLAMINE CETYL PHOSPHATE (UNII: 4UG0316V9S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TROLAMINE (UNII: 9O3K93S3TK)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ETHYL PARABEN (UNII: 14255EXE39)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0K00R)	42.35 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52664-003-01	12 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/01/2010	

Labeler - Hangzhou Facecare Cosmetics Co., Ltd. (545341856)

Registrant - Hangzhou Facecare Cosmetics Co., Ltd. (545341856)

Establishment

Name	Address	ID/FEI	Business Operations
Hangzhou Facecare Cosmetics Co., Ltd.		545341856	manufacture

Revised: 11/2010

Hangzhou Facecare Cosmetics Co., Ltd.