

ELF LIP BALM 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: 4.5%

Ethylhexyl Methoxycinnamate: 5.0%

Purpose:

Sunscreen

Uses:

Applying on lip area helps prevent sunburn

Warning:

For external use only

When Using This Product:

Avoid contact with eyes. If contact occurs rinse eyes thoroughly with water

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:

Apply liberally as often as needed before sun exposure.

Reapply as needed or after swimming or towel drying


Other Information

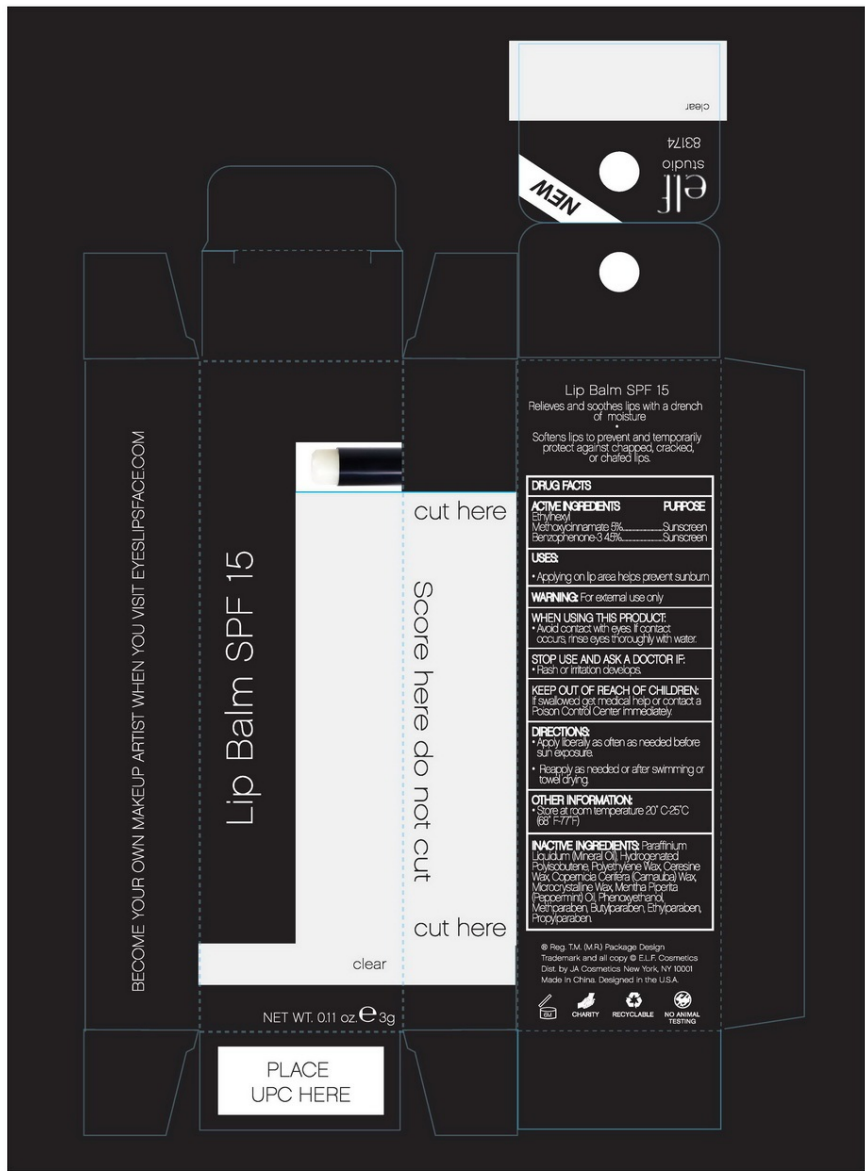
Store at room temperature 20-25 C (77-86F)

Inactive Ingredient:

Paraffinum Liquidum (Mineral Oil), hydrogenated Polyisobutene, Polyethylene Wax, Ceresine Wax, Copernicia Cerifera (Carnauba) Wax, Microcrystalline Wax, Mentha Piperita (Peppermint) Oil, Phenoxyethanol, Methylparaben, Butylparaben, Ethylparaben, Propylparaben.

labe

	DATE: 7/23/10
	COMMENTS: MATTE BLACK FINISH...AS EXISTING STUDIO LINE ADD INSERT
PROJECT: STUDIO LINE - 82601 LIP BALM SPF 15	
NEW SIZE BOX...SMALLER THAN ORIGINAL	



ELF LIP BALM SPF 15

oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52664-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4.5 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYISOBUTYLENE (1200000 MW) (UNII: FLT10CH37X)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	39.8 g in 100 g
PEPPERMINT OIL (UNII: AV092KU4JH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLPARABEN (UNII: 14255EXE39)	
BUTYLPARABEN (UNII: 3QPIIU3FV8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52664-008-01	3 g in 1 TUBE		

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.