

ELF SPF 45 SUNSCREEN UVA/UVB PROTECTION - titanium dioxide powder
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:

Titanium Dioxide: 21.25%

Zinc Oxide: 17%

Purpose:

Sunscreen

Uses:

Help prevent sunburns

Higher SPF gives more sunburn protection

Warning:

For external use only

When Using This Product:

Keep out of eyes. Rinse with water to remove.

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 as needed for 15-20 minutes of sun exposure

Other Information:

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


Inactive Ingredient:

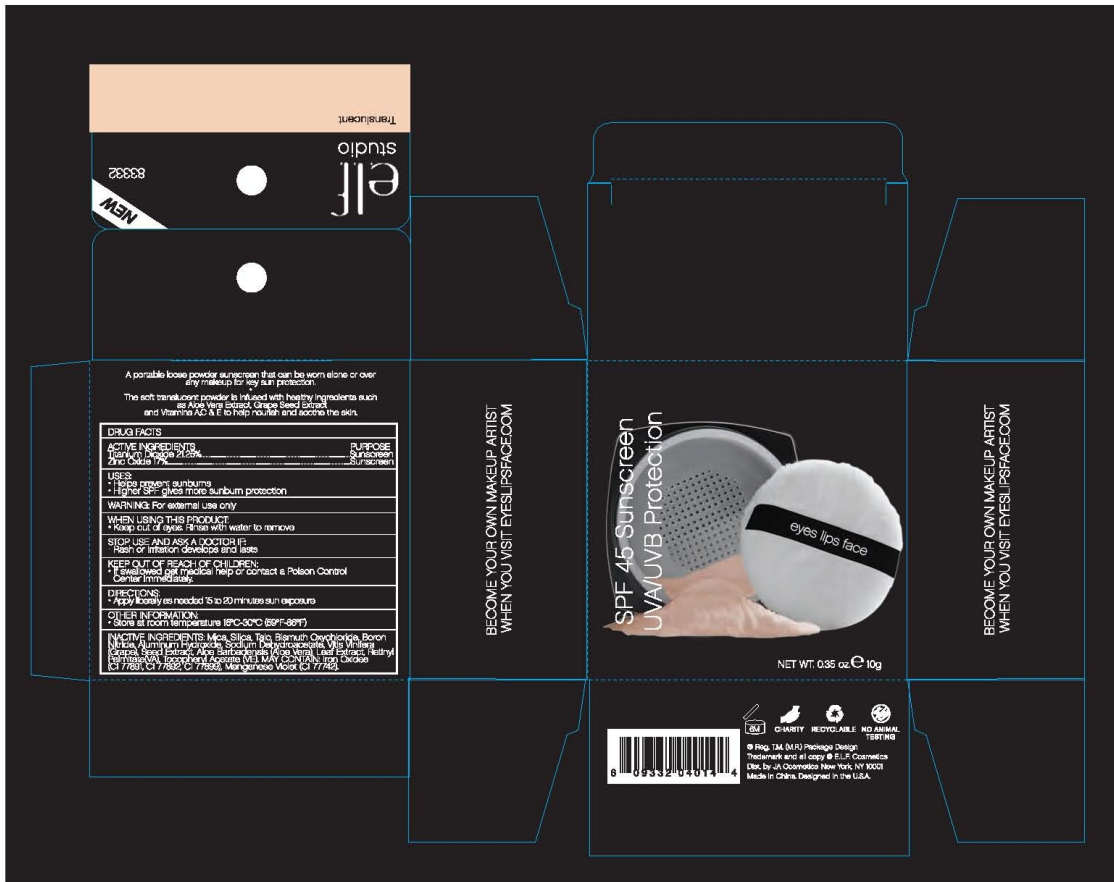
Mica, Silica, Talc, Bismuth Oxychloride, Boron Nitride, Aluminum Hydroxide, Sodium Dehydroacetate, Vitis Vinifera (Grape) Seed Extract, Aloe Barbadensis Leaf Extract, Retinyl Palmitate (VA), Tocopheryl Acetate (VE)

May contain:

Iron Oxides (CI 77491, CI 77492, CI 77499), Manganese Violet (CI 77742)

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|---|---|
|  | DATE: 7/22/10 |
| | COMMENTS: MATTE BLACK FINISH...AS EXISTING STUDIO LINE |
| PROJECT: STUDIO LINE - 83332 - SPF 45 Sunscreen | |
| W: 3.0" x H: 3.0" x D: 1.625" | |



ELF SPF 45 SUNSCREEN UVA/UVB PROTECTION

titanium dioxide powder

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52664-010 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|------------------|
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 21.25 g in 100 g |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 17 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| BISMUTH OXYCHLORIDE (UNII: 4ZR792I587) | |
| .ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) | |
| MICA (UNII: V8A1AW0880) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |
| FERROSFERRIC OXIDE (UNII: XM0M87F357) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| TALC (UNII: 7SEV7J4R1U) | |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) | |
| SODIUM DEHYDROACETATE (UNII: 8W46YN971G) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| GRAPE SEED OIL (UNII: 930MLC8XGG) | |
| VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|----------------------------|-----------------------------|---------------------------|
| 1 | NDC:52664-010-01 | 10 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 |

