# ALOE SUN BB SPF50 PLUS PA PLUS PLUS PLUS- zinc oxide, octinoxate, titanium dioxide, octis alate cream SKINFOOD 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.

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#### ACTIVE INGREDIENT

Active ingredient: ZINC OXIDE 5.41%, ETHYLHEXYL METHOXYCINNAMATE 5.00%, TITANIUM DIOXIDE 4.73%, ETHYLHEXYL SALICYLATE 3.50%

#### **INACTIVE INGREDIENT**

Inactive ingredient:

WATER, CYCLOPENTASILOXANE, BUTYLENE GLYCOL, CYCLOHEXASILOXANE, PEG-10 DIMETHICONE, PHENYL TRIMETHICONE, NIACINAMIDE, BUTYLENE GLYCOL DICAPRYLATE/DICAPRATE, TRIMETHYLSILOXYSILICATE, SODIUM CHLORIDE, DISTEARDIMONIUM HECTORITE, ALUMINUM HYDROXIDE, SORBITAN ISOSTEARATE, PROPYLENE GLYCOL, ALOE BARBADENSIS LEAF EXTRACT, STEARIC ACID, BEESWAX, HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER, DIMETHICONE, ALUMINA, VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER, ETHYLHEXYLGLYCERIN, OZOKERITE, TALC, PROPYLENE CARBONATE, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, SILICA SILYLATE, TRIETHOXYCAPRYLYLSILANE, DIMETHICONE/METHICONE COPOLYMER, HYALURONIC ACID, SILICA, ADENOSINE, PHENOXYETHANOL, FRAGRANCE, TITANIUM DIOXIDE (CI 77891), IRON OXIDES (CI 77492), IRON OXIDES (CI 77491), IRON OXIDES (CI 77499)

#### **PURPOSE**

PURPOSE: Sunscreen

#### **WARNINGS**

Warning: Skin Cancer/Skin Aging Alert

Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

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.

#### KEEP OUT OF REACH OF CHILDREN

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#### **USE**

USE:

Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

#### **DIRECTIONS**

#### **DIRECTIONS:**

Apply liberally 15 minutes before sun exposure. Reapply at least every 2 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.

#### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





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#### ALOE SUN BB SPF50 PLUS PA PLUS PLUS PLUS

zinc oxide, octinoxate, titanium dioxide, octisalate cream

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:76214-046 |
| Route of Administration | TOPICAL        |                    |               |

| Basis of Strength | Strength                                |
|-------------------|---|
| ZINC CATION       | 2.70 g in 50 g                          |
| OCTINOXATE        | 2.50 g in 50 g                          |
| TITANIUM DIO XIDE | 2.36 g in 50 g                          |
| OCTISALATE        | 1.75 g in 50 g                          |
|                   | ZINC CATION OCTINOXATE TITANIUM DIOXIDE |

| Inactive Ingredients               |          |
|------------------------------------|----------|
| Ingredient Name                    | Strength |
| WATER (UNII: 059QF0KO0R)           |          |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) |          |

| P | ackaging         |                     |                      |                    |
|---|------------------|---------------------|----------------------|--------------------|
| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:76214-046-01 | 50 g in 1 CARTON    |                      |                    |

| Marketing Information   |  |                      |                    |
|-------------------------|--|----------------------|--------------------|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part352                                  | 06/01/2014           |                    |
|                         |  |                      |                    |

### Labeler - SKINFOOD CO., LTD. (690324173)

## Registrant - SKINFOOD CO., LTD. (690324173)

| Establishment      |         |           |                        |  |
|--------------------|---------|-----------|------------------------|--|
| Name               | Address | ID/FEI    | Business Operations    |  |
| SKINFOOD CO., LTD. |         | 690324173 | manufacture(76214-046) |  |

Revised: 7/2014 SKINFOOD CO., LTD.