

FACE AND BODY SUNSCREEN- octinoxate and titanium dioxide lotion
Kareway Product, Inc.

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 Facts

Active Ingredients

Octyl Methoxycinnamate 7%

Titanium Dioxide 2.8%

Purpose

Sunscreen

Sunscreen

Use

helps prevent sunburn

Warnings

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 call a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
 - after 40 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- children under 6 months: Ask a doctor

Other information

- protect this product from excessive heat and direct sun
- may stain fabrics
- for Lot and Expiration Date, see crimp of tube

Inactive Ingredients

beeswax, carbomer, cetyl alcohol, dimethicone, disodium edta, fragrance, glycerin, glyceryl stearate se, glyceryl stearate and peg-100 stearate, methylparaben, propylene glycol, propylparaben, stearic acid, triethanolamine, water

Package label

Face and Body Sunscreen

Pure-Aid™

Face & Body

Sunscreen Lotion

SPF 30

Water Resistant(40 minutes)
Moisturizing with Aloe
Contains Vitamin E
Hypo-allergenic

3.5 oz (100mL)

FACE & BODY SUNSCREEN SPF30 is specially formulated to provide protection against sunburn. Hypo-allergenic, non-comedogenic and water resistant formula moisturizes and yet won't clog pores.

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|---------------------------|----------------|
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Inactive ingredients : Beeswax, Carbomer, Cetyl alcohol, Dimethicone, Disodium EDTA, Fragrance, Glycerin, Glyceryl stearate, Glyceryl stearate and Peg-100 stearate, Methylparaben, Propylene glycol, Propylparaben, Stearic acid, Triethanolamine, Water

Made In Korea

KAREWAY

Exclusively distributed by:
Kareway Product, Inc.
Compton, CA 90220

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FACE AND BODY SUNSCREEN

octinoxate and titanium dioxide lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:67510-0081 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 7 g in 100 mL |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 2.8 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| YELLOW WAX (UNII: 2ZA36H0S2V) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| WATER (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|------------------------------|--|----------------------|----------------------|--------------------|
| 1 | NDC:67510-0081-5 | 100 mL in 1 TUBE | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part352 | 01/24/2013 | | |

Labeler - Kareway Product, Inc. (121840057)

Revised: 2/2013

Kareway Product, Inc.