

KIDS 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/Early 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

Pure Aid Kids Sunscreen Lotion

Pure-Aid™

Kids

Sunscreen Lotion

SPF 30

Water Resistant
(40 minutes)
Hypo-allergenic

3.5 oz (100mL)

KIDS SUNSCREEN SPF30 is specially formulated to provide protection against sunburn. With ultra water resistant formula, it is great for kids who love water.

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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

KARWAY

Exclusively distributed by:
Karaway Product Inc.
Compton, CA 90229

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KIDS SUNSCREEN

octinoxate and titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0082
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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0082-5	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	12/01/2011	

Labeler - Kareway Product, Inc. (121840057)

Revised: 2/2013

Kareway Product, Inc.