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:
- o 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

Water, Glycerin, Glyceryl Stearate,
PEG-100 Stearate, Stearic acid, Cetearyl Alcohol, Phenoxyethanol,
Acrylates/C10-30 alkyl acrylate crosspolymer, Chlorphenesin,
Triethanolamine, Lavandula Angustifolia (Lavender) Extract,
Salvia Sclarea (Clary) Extract, Hyacinthus Orientalis Extract,
Chamomilla Recutita (Matricaria) Flower/Leaf Extract, Borago
officinalis Extract, Centaurea cyanus flower Extract, Dimethicone,
Butylene Glycol, 1,2-Hexanediol, Ethylhexylglycerin, Disodium
EDTA, Fragrance

Package label

Pure Aid Kids Sunscreen Lotion



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

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Exclusively distributed by: Kareway Product Inc. 2550 S. Dominguez Hills Dr. Compton, CA 90220

Made in Korea







Sunscreen Lotion

SPF 30

Water Resistant (40 minutes) Hypo-allergenic

3.5 oz (100mL)

KIDS SUNSCREEN

octinoxate and titanium dioxide lotion

Product Information

HUMAN OTC DRUG Product Type Item Code (Source) NDC:67510-0082

TOPICAL Route of Administration

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 g in 100 mL			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	2.8 g in 100 mL			

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
EDETATE DISODIUM ANHYDROUS (UNII: 8 NLQ36 F6 MM)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
1,2-HEXANEDIO L (UNII: TR0 46 Y3K1G)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
CHLORPHENESIN (UNII: 1670 DAL4SZ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:67510-0082-5	100 mL in 1 TUBE; Type 0: Not a Combination Product	12/0 1/20 11		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part352	12/0 1/20 11			

Labeler - Kareway Product, Inc. (121840057)

Revised: 10/2019 Kareway Product, Inc.