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





FACE AND BODY SUNSCREEN

octinoxate and titanium dioxide lotion

Product Information						
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:67510-0081			
Route of Administration	TOPICAL	DEA Schedule				

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
OCTINOXATE (OCTINOXATE)	OCTINOXATE	7 g in 100 mL			
TITANIUM DIO XIDE (TITANIUM DIO XIDE)	TITANIUM DIO XIDE	2.8 g in 100 mL			

Inactive Ingredients					
Ingredient Name	Strength				
YELLOW WAX					
CETYL ALCOHOL					
DIMETHICONE					
EDETATE DISO DIUM					
GLYCERIN					
GLYCERYL MONOSTEARATE					
PEG-100 STEARATE					
METHYLPARABEN					
PROPYLENE GLYCOL					
PROPYLPARABEN					
STEARIC ACID					
TROLAMINE					
WATER					

Packaging

# Item Code	Package Description	Marketing	Start Date	Mar	keting 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		0 1/24/20 13					

Labeler - Kareway Product, Inc. (121840057)

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