YES TO CUCUMBERS NATURAL SUNSCREEN SPF 40 KIDS- zinc oxide, titanium dioxide lotion

Autumn Harp, 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.

Yes To Cucumbers Natural Sunscreen SPF 40 Kids

Active Ingredient

Zinc Oxide (11.7%) Titanium Dioxide (5.5%)

Purpose

Sunscreen

Uses

Helps prevent sunburn • Higher SPF gives more sunburn protection • Provides high protection against sunburn

Warnings:

For external use only. When using this product avoid contact with eyes • if contact occurs, rinse with water to remove. **Stop use and ask Doctor** if rash or irritation develops and lasts. **Keep out or reach of children.** If swallowed, get medical help or contact a Poison Control Center Immediately.

Directions

Apply liberally and evenly 15 minutes before sun exposure • reapply after 40 minutes of swimming or sweating, immediately after towel drying and at least every 2 hours • children under 6 months of age, ask doctor

Sun Protection Measure Spending Itime in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with Broad Spectrum SPF value of 15 or higher and other sun measures including: Limit time in the sun, especially from 10am - 2pm. Wear long-sleeved shirts, pants, hats, and sun-glasses.

Inactive Ingredients

Water, Ethylhexyl Palmitate, Carthamus Tinctorius (Safflower) Seed Oil, Polyglyceryl-6 Polyricinoleate, Glycerin, Aluminum Hydroxide, Phenethyl Alcohol, Sodium Chloride, Glyceryl Caprylate, Polyglyceryl-10 Laurate, Triethoxycaprylylsilane, Fragrance, Hydrated Silica, Tocopherol, Alcohol, Aloe Barbadensis Leaf Juice, Cucumis Sativus (Cucumber) Seed Extract*, Camellia Sinensis (Green Tea) Leaf Extract, Citric Acid, Potassium Sorbate, Sodium Benzoate. * Certified Organic Ingredient

Principal Display Panel

Image Components



YES TO CUCUMBERS NATURAL SUNSCREEN SPF 40 KIDS

zinc oxide, titanium dioxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51514-0316
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	11.7 g in 100 mL
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	5.5 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
POLYGLYCERYL-6 DIOLEATE (UNII: 062SZD3F3X)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)	
PHENETHYL ALCOHOL (UNII: ML9LGA7468)	
SO DIUM CHLO RIDE (UNII: 451W47IQ8X)	
POLYGLYCERYL-10 LAURATE (UNII: MPJ2Q8WI8G)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)	
CUCUMBER (UNII: YY7C30VXJT)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALCOHOL (UNII: 3K9958V90M)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
SO YBEAN OIL (UNII: 241ATL177A)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CUCUMBER SEED (UNII: BT3S9L53JK)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:51514-0316-1	85 mL in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/30/2012	

Labeler - Autumn Harp, Inc. (064187883)

Establishment				
Name	Address	ID/FEI	Business Operations	
Autumn Harp, Inc.		064187883	manufacture(51514-0316)	

Revised: 9/2013 Autumn Harp, Inc.