AG LINEA HAND SANITIZER- ethyl alcohol gel Natural Dyes 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.

AG LINEA HAND SANITIZER

Drug Facts

Active ingredient

Ethyl Alcohol 70%

Purpose

Antiseptic

Uses

- To decrease bacteria on the skin that could cause disease.
- When water, soap and towel are not available.
- Recommended for repeated use.

Warnings

For external use only: hands.

Flammable. Keep away from fire or flame.

When using this product • Keep out of eyes, ears, or mouth. • In case of eye contact, flush eyes thoroughly with water. • Avoid contact with broken skin. • Do not inhale or ingest.

Stop use and ask a doctor if • redness or irritation develop

• condition persists for more than 72 hours

Keep out of reach of children.

• Children should be supervised by an adult when using this product. • If swallowed, get medical help or contact a Poison Control Center right away.

Directions

• Wet hand thoroughly with product and allow to dry without wiping. • No rinsing required. • For children under 6, use only under adult supervision. • Not recommended for infants.

Other information

• Store below 105°F(40°C). • May discolor certain fabrics. • Harmful to wood finishes & plastics

Inactive ingredients:

Water(Aqua), Triethanolamine, Carbomer, Aloe Barbadensis(Aloe Vera) Gel, Fragrance, Glycerin, Propylene Glycol, Tocopheryl Acetate(Vitamin E).

Distributed by:

Natural Dyes Inc.

New York, NY 10018

Made in China

UPC CODE

Kills 99.9% of Germs

ADVANCED MOISTURIZING FORMULA WITH ALOE AND VITAMIN E

IHOW TO USE HAND SANITIZER

Dispense a coin sized drop of sanitizer on your palm.

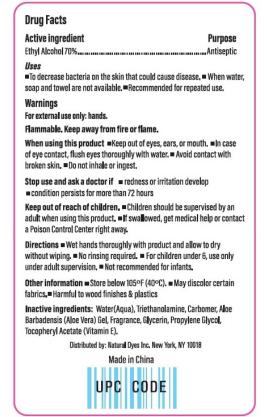
Spread the sanitizer and rub palms together.

Rub sanitizer on palms, between fingers, finger tips, and back of hands.

Rub hands together for 20 seconds until sanitizer dries.

Packaging







HAND SANITIZER

KILLS 99.9% OF GERMS **ADVANCED MOISTURIZING** FORMULA WITH ALOE **AND VITAMIN E**

8 FL OZ. (237 mL)

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Purpose

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HAND **SANITI7FR**

KILLS 99.9% OF GERMS ADVANCED MOISTURIZING FORMULA WITH ALOE AND VITAMIN E

16.9 FL OZ (500 mL)

dients: Water(Aqua), Triethanolami loe Vera) Gel, Fragrance, Glycerin, Pr

UPC CODE

AG LINEA HAND SANITIZER

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77781-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Alcohol (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	Alcohol	70 mL in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
TROLAMINE (UNII: 9O3K93S3TK)			
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:77781-001-04	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2020		
2	NDC:77781-001-01	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2020		
3	NDC:77781-001-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/30/2020		

Labeler - Natural Dyes Inc (078772235)

Establishment				
Name	Address	ID/FEI	Business Operations	
Taizhou Huangyan Liweir Cosmetic Technology LTD		560781517	manufacture (77781-001)	

Establishment					
Name	Address	ID/FEI	Business Operations		
Sanrace Biotechnology Co., Ltd.		543000938	manufacture(77781-001)		

Revised: 8/2020 Natural Dyes Inc