HAND SANITIZER- ethyl alcohol gel
Reneotech 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.

Handsanitizer

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

a. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
b. Glycerol (1.45% v/v).
c. Hydrogen peroxide (0.125% v/v).
d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Ethlyl Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Uses

- To decrease bacteria on the skin that could cause disease
- Recommended for repeat use

Warnings

For external use only. Flammable. Keep away from fire or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product

- Keep out of eyes, incased of contact with eyes, flush thoroughly with water
- Avoid contact with broken skin
- Do not inhale or ingest

Stop use and ask a doctor if

- Irritation and redness develop
- Condition persists for more than 72 hours

Keep out of reach of children

- . If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Directions

- Wet hands thoroughly with product and allow to dry without wiping
- For Children under 6, use only under adult supervision
- Not recommended for infants

Other information

- Do not store above 105°F
- May discolor some fabrics
- Harmful to woodfinishes and plastics

Inactive ingredients

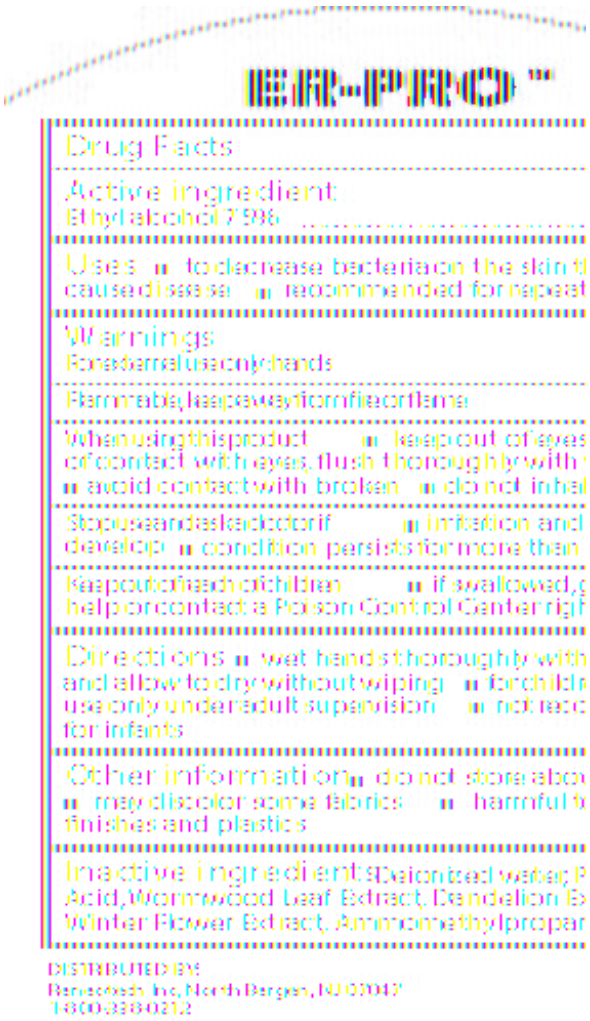
Deionized Water, Polyacrylic Acid, Wormwood Leaf Extract, Dandelion Extract, Aminomethyl Propanol.

Package Label - Principal Display Panel

- 59.1471 ml NDC: 79991-001-05
-


ER-Pro
Advanced
Hand Sanitiz
75% Ethyl Alcohol
Kil
mare
ee ee
ger
Contains
Skin Protective
Plant Extracts
2 fl oz (60 ml)

-



- 236.588 ml NDC: 79991-001-08
-


er-Pro
Advanced
Hand Sanitiz
75% Ethyl Alcohol
Kil
more
99.99
ger
Contains
Skin Protective
Plant Extracts
8 fl oz (240ml)

Drug Facts

Active ingredient

Ethyl alcohol 75% .....

Uses ■ to decrease bacteria on the skin that could cau
■ 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. In case
with eyes, flush thoroughly with water ■ avoid contact w
skin ■ do not inhale or ingest

Stop use and ask a doctor if ■ irritation and redness
■ condition persists for more than 72 hours

Keep out of reach of children ■ if swallowed, get medica
contact a Poison Control Center right away

Directions ■ wet hands thoroughly with product and
without wiping ■ for children under 6, use only under ad
supervision ■ not recommended for infants

Other information ■ do not store above 105°F ■
some fabrics ■ harmful to wood finishes and plastics

Inactive ingredients Deionized water, Polyacrylic
Wormwood Leaf Extract, Dandelion Extract and Aminon
-propanol.

DISTRIBUTED BY:
Reneotech Inc,

North Bergen, NJ 07047
1-800-338-0212

8 53904

Exp:

- 480 ml NDC: 79991-001-10
-


er-Pro
Advanced
Hand Sanitiz
75% Ethyl Alcohol
Kil
more
99.99
ger
Contains
Skin Protective
Plant Extracts
16 floz (480ml)

Drug Facts

Active ingredient

Ethyl alcohol 75% .....

Uses ■ to decrease bacteria on the skin that could cau
■ 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. In case
with eyes, flush thoroughly with water ■ avoid contact w
skin ■ do not inhale or ingest

Stop use and ask a doctor if ■ irritation and redness
■ condition persists for more than 72 hours

Keep out of reach of children ■ if swallowed, get medica
contact a Poison Control Center right away

Directions ■ wet hands thoroughly with product and
without wiping ■ for children under 6, use only under ad
supervision ■ not recommended for infants

Other information ■ do not store above 105°F ■
some fabrics ■ harmful to wood finishes and plastics

Inactive ingredients Deionized water, Polyacrylic
Wormwood Leaf Extract, Dandelion Extract and Aminon
-propanol.

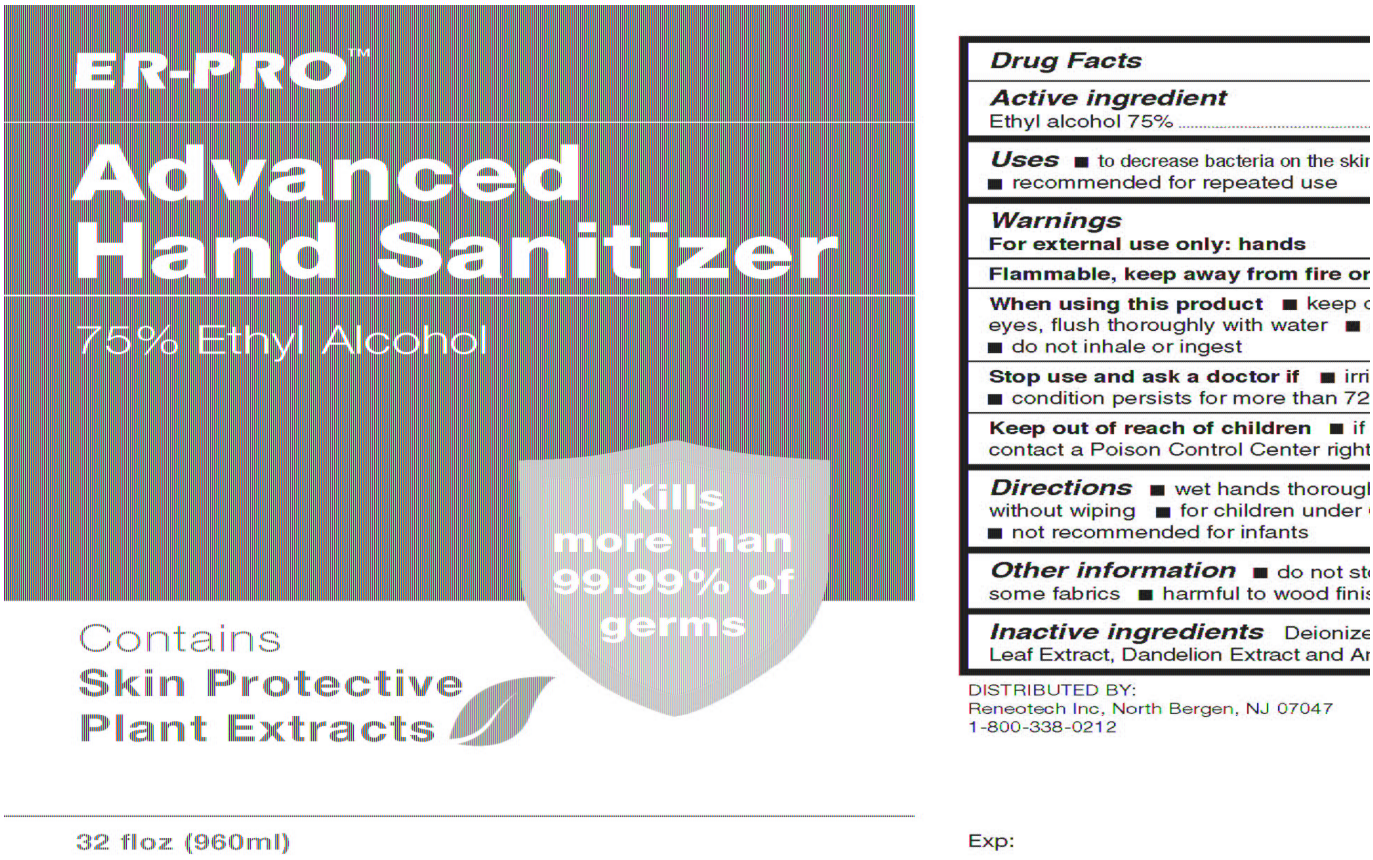
DISTRIBUTED BY:
Reneotech Inc,

North Bergen, NJ 07047
1-800-338-0212

8 53904

Exp:

- 946.353 ml NDC: 79991-001-12
-



HAND SANITIZER

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79991-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 75 mL

Inactive Ingredients

Ingredient Name	Strength
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
WORMWOOD (UNII: F84709P2XV)	
WATER (UNII: 059QF0KO0R)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
TARAXACUM OFFICINALE ROOT (UNII: 9DE5YCO0RU)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79991-001-08	236.588 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:79991-001-12	946.353 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:79991-001-05	59.1471 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:79991-001-10	473.176 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Reneotech Inc (035133223)

Registrant - Shantou Kangjie Daily Chemical Industry Co., Ltd (527128712)

Establishment

Name	Address	ID/FEI	Business Operations
Reneotech Inc		035133223	label(79991-001)

Establishment

Name	Address	ID/FEI	Business Operations
Shantou Kangjie Daily Chemical Industry Co., Ltd		527128712	manufacture(79991-001)

Revised: 8/2020 Reneotech Inc