# HAND SANITIZER- alcohol liquid HANUL CO.,LTD

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.

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#### hand sanitizer gel Rico 500ml

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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (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)

Alcohol 80% v/v. Purpose: Antiseptic

#### **Purpose**

Antiseptic, Hand Sanitizer

#### Use

to decrease bacteria on the skin that can cause disease.

#### Warnings

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

When using the product keep out of eyes. In case 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 or redness develops 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**

Place enough product to hands to cover all surface

Rub hands together until dry

Not recommended for infants

#### Other information

do not store above105°F/40°C May discolor some fabrics Harmful to wood finishes and plastics

### **Inactive ingredients**

Water. Glycerin, Hydrogen peroxide, Carbomer, Aminomethyl Propanol, Fragrance

## Package Label - Principal Display Panel

500 mL NDC: 75214-502-50

Rico

Hand sanitizer

non-sterile solution

80% alcohol antiseptic

kill 99.9% germs of common illness-causing germs

## RICO Hand Sanitizer (500ml Gel)





#### HAND SANITIZER

alcohol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75214-502	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.13 mL in 100 mL		
WATER (UNII: 059QF0KO0R)	17.68 mL in 100 mL		
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	0.4 mL in 100 mL		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.3 mL in 100 mL		

Packaging				
# Item Code Package Description		Marketing Start Date	Marketing End Date	
1	NDC:75214-502- 50	500 mL in 1 BOTTLE, DISPENSING; 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 - HANUL CO.,LTD (557814370)

Establishment				
Name	Address	ID/FEI	Business Operations	
HANUL CO.,LTD		557814370	manufacture(75214-502)	

Revised: 5/2020 HANUL CO.,LTD