

## **HAND SANITIZER- alcohol gel**

### **Revler, 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.*

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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)

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, 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
- c. Hydrogenated Castor Oil
- d. Sterile distilled water or boiled cold water.
- e. Carbomer
- f. Phenoxyethanol
- g. Benzyl Alcohol
- h. Sodium Hydroxide
- i. Fragrance (parfum)

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 70% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

### **Use**

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

### **Warnings**

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

### **Do not use**

- Do not use in on open skin wounds.

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right

away.

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**Directions**

- • Apply enough product to thoroughly cover hands. Rub hands together until dry.

**Other information**

- Do not store above 110°F(43°C).

**Inactive ingredients**

Water(Aqua),Glycerin,PEG-40 Hydrogenated Castor Oil, Carbomer, Phenoxyethanol, Fragrance (parfum), Benzyl Alcohol ,Sodium Hydroxide

**Package Label - Principal Display Panel**

# HYAKU OKU

ヒャクオク  
ハンドサニタイザー



2 fl. oz / 60 ml

## HYAKU OKU **HAND SANITIZER**

Active Ingredients	Purpose
Alcohol Denat.70% .....	Antibacterial

**INACTIVE INGREDIENTS:** Water(Aqua),Glycerin, PEG-40 Hydrogenated Castor Oil, Carbomer, Phenoxyethanol, Fragrance (parfum), Benzyl Alcohol ,Sodium Hydroxide.

**USE[S]** Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

**DIRECTIONS:** Apply enough product to thoroughly cover hands. Rub hands together until dry.

**WARNINGS:** For external use only. Flammable. Keep away from heat or flame Do not use on open skin wounds. When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. May discolor certain fabrics or surfaces.

**OTHER INFORMATION:** Do not store above 110°F(43°C).

Distributed By:  
Revler inc,539 W.Commerce,  
TX 75208



75257-170-06

60 mL NDC: 75257-170-06

**HAND SANITIZER**

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75257-170
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
CARBOMER 1342 (UNII: 809Y72KV36)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:75257-170-06	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

### Marketing Information

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

**Labeler** - Revler, Inc (080974712)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Larry (Xiamen) Hi-Tech Co., Ltd.		529759328	manufacture(75257-170)

Revised: 4/2020

Revler, Inc