

**WIPE- wipe dressing**  
**SHANDONG AISHULE HYGIENE PRODUCTS 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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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)**

Isopropyl Alcohol 75% 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**

- in children less than 2 months of age
- 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**

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

### **Other information**

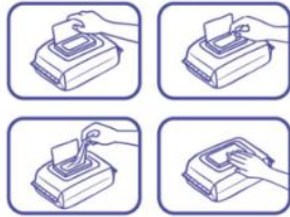
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

### **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

### **Package Label - Principal Display Panel**

300 ml NDC: 82061-005-01




**Instructions**

- ① Open the outer cover, uncover the sticker on the outer package, and take out the wipes for use.
- ② Put the sticker back on to prevent the wipes from drying out

Manufacturer: SHANDONG AISHULE HYGIENE PRODUCTS CO., LTD  
 Address: Northwest Corner, Qiyang Road and Industrial Three Road intersection, High-tech Zone, Linyi, Shandong, CHINA  
 Tel: 400-605-3916  
 Specifications: 10PCS/ 1bag

**Product name:** WIPE  
**Active ingredient[s]:** 75%Alcohol  
**Inactive ingredients:** spunlace nonwoven, purified water USP  
**Use[s]:** Health care personnel hand rub to help reduce bacteria that potentially can cause disease  
**Warnings:**  
 1) For external use only. Flammable. Keep away from heat or flame  
 2) Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.  
 3) Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.  
 4) Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222  
**Do not use:** 1) in children less than 2 months of age  
 2) on open skin wounds  
**Note:** It's insoluble in water. Please put it in the garbage can after use;  
 Store between 15-30C (59-86F); and keep in the shade.  
**Shelf life:** 24 months



**WIPE**

wipe dressing

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82061-005
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	25 mL in 100 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

<b>1</b>	NDC:82061-005-01	300 mL in 1 PATCH; Type 0: Not a Combination Product	12/01/2020	
<b>Marketing Information</b>				
<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		12/01/2020	

**Labeler** - SHANDONG AISHULE HYGIENE PRODUCTS CO., LTD (541645991)

**Registrant** - SHANDONG AISHULE HYGIENE PRODUCTS CO., LTD (541645991)

### Establishment

Name	Address	ID/FEI	Business Operations
SHANDONG AISHULE HYGIENE PRODUCTS CO., LTD		541645991	manufacture(82061-005)

Revised: 6/2021

SHANDONG AISHULE HYGIENE PRODUCTS CO., LTD