75% ALCOHOL WIPES- 75% alcohol wipes cloth Winner Medical (Jiayu) 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.

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

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

208.8 ml NDC: 71870-013-01





EAN 13

Manufacturer
Winner Medical (Jiayu) Co., Ltd.
Address: Number 172 Fenghuang Avenue, Jiayu, Xianning, Hubei, China
Tel: 0715-6334688 Fax: 0715-6335188 Post code: 437200
Made In China

To report a serious adverse event, contact: Winner Medical Co.,Ltd c/o 144 Research Drive, Hampton, VA 23666 Made in china





75% Alcohol Hand Sanitizing Wipes

- For personal hand hygiene to help prevent the spread of bacteria and germs
- Enriched with Aloe Vera

Drug Facts			
Active Ingredient Ethyl alcohol 75% v/v		PurposeAntiseptic	
Uses: Hand sanitizing wipes to help reduce bacteria that pe	Jses: land sanitizing wipes to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.		
Warning: 1. Flammable. Keep away from heat or flame. 2. For external use only. Avoid contact with eyes, ears and mouth. If contact occurs, rinse thoroughly with water. Stop use and consult a doctor if imitation devel 3. Keep out of reach of children. If swallowed, cet medical help or contact a poison control center right away.			
Do not use 1. In children less than 2 months of age.	On open skin wounds.	Not use if you are allergic to any of the ingredients	
Directions: 1. Open the label, take out the wet wipes and use it to clean. 2. Place enough product on hands to cover all surfaces. Rub hands together until dry. 3. Supervise children when they use this product. Other Information - Store between 15-30°C (59-86F) - Avoid exposing to direct sunlight.			
			Inactive ingredients Also harbariensis leaf extract Purified Water

75% ALCOHOL WIPES

75% alcohol wipes cloth

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Product	Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71870-013

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

inactive ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		

Packaging

ı	- · 0 0			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:71870-013-	208.8 mL in 1 BAG; Type 0: Not a Combination Product	10/12/2020	

Marketing Information

wai keing moi maton			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/12/2020	

Labeler - Winner Medical (Jiayu) Co., Ltd. (530058569)

Revised: 10/2020 Winner Medical (Jiayu) Co., Ltd.