ALCOHOL WIPES- alcohol wipes cloth Tianjin Shurou Sanitary 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.

ALCOHOL WIPES

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)

Alcohol 70%v/v Purpose: Antiseptic

Purpose

Antiseptic

Use

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

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

Warnings

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

Do not use

in children less than 6 years 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. 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.

Directions

Supervise children under 6 years of age when using this product to avoid swallowing.

Inactive ingredients

Parfum, purified water, spunlace nonwoven

Package Label - Principal Display Panel



ALCOHOL WIPES

alcohol wipes cloth **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:76969-006 TOPICAL, CUTANEOUS **Route of Administration Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII: 3K9958V90M) ALCOHOL 70 g in 100 g **Inactive Ingredients Ingredient Name** Strength WATER (UNII: 059QF0KO0R) Packaging

# Item Code		Package Description	Marketing Start Date	Marketing End Date			
1 NDC:76969-006-0	01 10	0 g in 1 BOX; Type 0: Not a Combination Product	03/30/2020				
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Marketing In	for	nation					
Marketing In Marketing Categ		nation Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
0	ory		Marketing Start Date 03/30/2020	Marketing End Date			

Labeler - Tianjin Shurou Sanitary Products Co., Ltd (554531083)

Establishment

Name	Address	ID/FEI	Business Operations
Tianjin Shurou Sanitary Products Co., Ltd		554531083	manufacture(76969-006)

Revised: 5/2020

Tianjin Shurou Sanitary Products Co., Ltd