XS WIPE 75% ETHANOL- alcohol liquid **Tidy Non-Woven SDN.BHD**

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.

XS Wipe 75% Ethanol

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

Active Ingredient(s)

Alcohol 75% Ethanol v/v. Purpose: Antiseptic

Purpose

XS 湿巾桶装80片

296mm



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.

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

- 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

purified water USP

Package Label - Principal Display Panel

XS 湿巾桶装80片

296mm



XS WIPE 75% ETHANOL

alcohol liquid

Product Type HUMAN OTC DRUG	Item Code (Source) NDC:8	0576-100
Route of Administration 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: 059 QF0 KO0 R)	25 mL in 100 mL			

Pá	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1 NDC:80576-100-01 1 m				
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
Marketing Category OTC monograph not final	Application Number or Monograph Citation part333A	Marketing Start Date 09/04/2020	Marketing End Date	

Labeler - Tidy Non-Woven SDN.BHD (894020978)

Registrant - Tidy Non-Woven SDN.BHD (894020978)

Establishment					
Name	Address	ID/FEI	Business Operations		
Tidy Non-Woven SDN.BHD		894020978	manufacture(80576-100)		

Revised: 9/2020 Tidy Non-Woven SDN.BHD