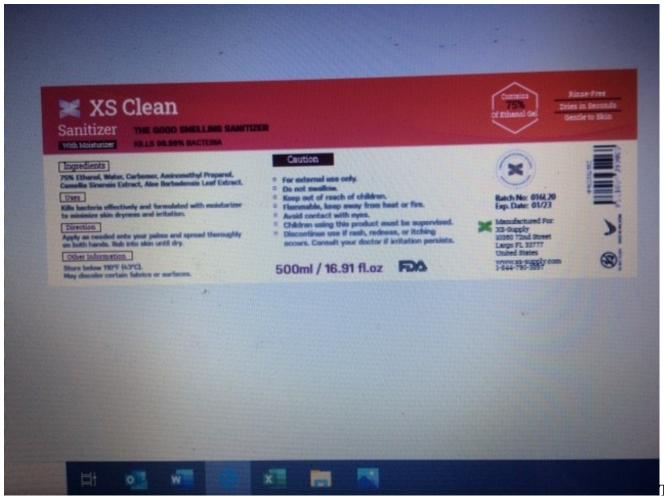
#### XS CLEAN 75% ETHANOL- alcohol liquid Tidy Non-Woven SDN.BHD

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.

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#### XS Clean 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
- b. NDC 80576-900

#### Active Ingredient(s)

Alcohol 75% Ethanol v/v. Purpose: Antiseptic

#### Purpose

## 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.

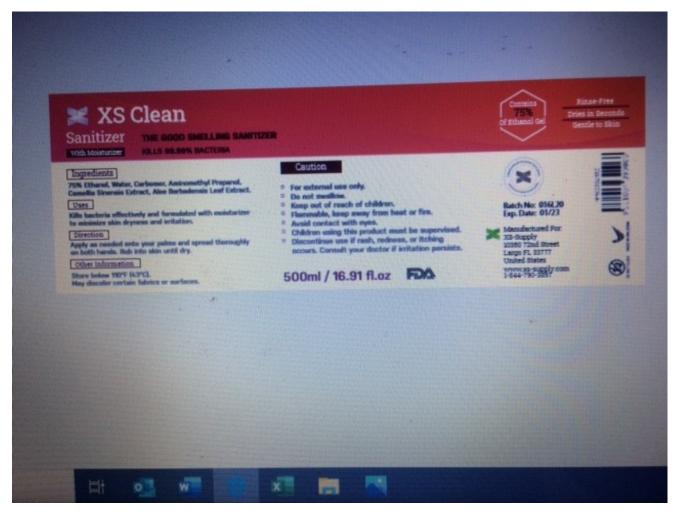
## Other information

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

## **Inactive ingredients**

purified water USP

## Package Label - Principal Display Panel



Inactive Ingredients Ingredient Name Strength WATER (UNII: 059QF0K00R) 25 mL in 100 mL Packaging	<b>KS CLEAN 75% ETHANOL</b>							
Human Orc DRUG Hem Code Deltation     Route of Administration TOPICAL     TOPICAL Envice of Administration   Autor of Administration   TOPICAL Envice of Administration   Autor of Administration   TOPICAL Envice of Administration   Autor of Administration   TOPICAL Envice of Administration   Topical Statements   Topical Statements Strength   Strengthered Strength   AlcoHol Cunit: 3K9958900(Alcone) AlcoHol Cunit: Strength   Strengthered Strength   Strength AlcoHol Cunit: Strength   Strengthered Strength   Strength Strength   Strength Strength Strength Strength Strength Strength Strength Strength Strength Strength Strength Strength Strength Strength Strength Strength Strength Strength Strength Strength Strength Strength Strength Strength Strength Strength Strength	alcohol liquid							
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TOPICAL   Active Ingredient/Active Moiety   Ingredient Name   Actor (UNII: 3K-958V90M) (ALCOHOL - UNII:3K9958V90M)   ALCOHOL (UNII: 3K-958V90M) (ALCOHOL - UNII:3K9958V90M)   Actor (UNII: 3K-958VF)   Actor (UNII: 3K-959VF)   Actor (UNII: 3K-959VF) <th>Product Informa</th> <th>tion</th> <th></th> <th></th> <th></th> <th></th>	Product Informa	tion						
Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M) ALCOHOL 75 mL in 100 mL Inactive Ingredients Ingredient Name Strength WATER (UNII: 059QF0K0R) 25 mL in 100 mL Packaging # Item Code Package Description Marketing Start Date Marketing End D	Product Type		HUMAN OTC DRUG	Item Code (Source) NDC:80576-900		NDC:80576-900		
Ingredient Name       Basis of Strength       Strength         ALCO HOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)       ALCOHOL       75 mL in 100 mL         Inactive Ingredients       Ingredient Name       Strength         Inactive Ingredients       Ingredient Name       Strength         VATER (UNII: 059QF0K00R)       25 mL in 100 mL       100 mL         Packaging       Item Code       Package Description       Marketing Start Date       Marketing End D	Route of Administra	ntion	TOPICAL					
Ingredient Name       Basis of Strength       Strength         ALCO HOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)       ALCOHOL       75 mL in 100 mL         Inactive Ingredients       Ingredient Name       Strength         Inactive Ingredients       Ingredient Name       Strength         VATER (UNII: 059QF0K00R)       25 mL in 100 mL       100 mL         Packaging       Item Code       Package Description       Marketing Start Date       Marketing End D								
Ingredient Name       Basis of Strength       Strength         ALCO HOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)       ALCOHOL       75 mL in 100 mL         Inactive Ingredients       Ingredient Name       Strength         Inactive Ingredients       Ingredient Name       Strength         VATER (UNII: 059QF0K00R)       25 mL in 100 mL       100 mL         Packaging       Item Code       Package Description       Marketing Start Date       Marketing End D								
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WATER (UNII: 059QF0K00R)       25 mL in 100 mL         Packaging         #       Item Code       Package Description         Marketing Start Date       Marketing End D	Inactive Ingredie	ents						
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#       Item Code       Package Description       Marketing Start Date       Marketing End D	WATER (UNII: 059QF0KO0R)				25 mL in 100 mL			
#       Item Code       Package Description       Marketing Start Date       Marketing End D								
#       Item Code       Package Description       Marketing Start Date       Marketing End D								
	Packaging							
1 NDC:80576-900-01 1 mL in 1 CANISTER: Type 0: Not a Combination Product 10/06/2020	# Item Code		Package Description	I	Marketing Start Date	Marketing End Date		
1 in the second se	1 NDC:80576-900-01	1 mL in 1 CANIS	TER; Type 0: Not a Combinatio	n Product 1	10/06/2020			

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph not final	part333A	07/01/2020					

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

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

# Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
Tidy Non-Woven SDN.BHD		894020978	manufacture(80576-900)

Revised: 10/2020

Tidy Non-Woven SDN.BHD