

## **ANTI GERM- isopropyl 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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### **Anti Germ Hand Wipe**

#### **Anti Germ**

+CThis 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 (70%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. 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.

#### **Anti Germ Active Ingredient 70% Isopropyl alcohol**

Isopropyl Alcohol 70% 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.

Anti Germ Label-1

#### **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

**USE:**

- Close the cap, pull the tissue until tears off.
- Close lid immediately after use to preserve moisture of wipes.

**ANTI-GERM™**

THE MOST COMMON, AND WIDELY USED WIPE

- Cleans and sanitizes hands
- Kills 99.99% of germs



**ACTIVE INGREDIENTS**

Alcohol 70% by Volume.....  
Isopropyl Alcohol

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**Uses**

Hand sanitizer to help reduce bacteria on skin that could cause

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**Warnings**

- Flammable, keep away from fire or flame.
- For external use only.
- Do not use in or contact the eyes.
- Discontinue use if irritation and redness develop. If conditions worsen, consult a physician.
- Keep this out of reach of children unless under adult supervision.
- If swallowed, get medical help or contact a Poison Control Center.

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**Directions**

- To start feed: Remove cover and discard seal from container. Wipe corner, tear off first wipe for use. Twist next wipe to hole in the container cover. Pull through about one inch. Re-use and soap off at a 90° angle. Keep cap closed to prevent drying.
- Wipe hands, fingers, interdigital areas and wrists thoroughly the entire wipe surface. Allow to dry.
- If hands are visibly soiled or contaminated, use first wipe to sanitize with a second wipe.
- Discard after single use.
- Ideal for hand sanitization when soap and water are not available.

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**Inactive Ingredients**

Water

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**Other Informations**

Lot No. and Expiration Date can be found on canister

**AFTER:**



purified water

70% Isopropyl Alcohol

CONTAINS 100 WIPES



SIZE 5.1 in x 7.1 in

Net Wt. 13.19 Oz (373.9g)

**Manufactured By:**  
**TIDY NON-WOVEN SI**  
LOT PTD 5408 (P.L.O 162), Jc  
Tanjung Agas Industrial Esta  
Johor, Malaysia.  
Website: www.tidynonwoven  
E-mail: nonwoven@tidy.net






### Package Label - Principal Display Panel

**USE:**

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<b>ACTIVE INGREDIENTS</b>
Alcohol 70% by Volume.....
Isopropyl Alcohol
<b>Uses</b>
Hand sanitizer to help reduce bacteria on skin that could cause
<b>Warnings</b>
<ul style="list-style-type: none"> <li>Flammable, keep away from fire or flame.</li> <li>For external use only.</li> <li>Do not use in or contact the eyes.</li> <li>Discontinue use if irritation and redness develop. If condition persists, consult a physician.</li> <li>Keep this out of reach of children unless under adult supervision.</li> <li>If swallowed, get medical help or contact a Poison Control Center.</li> </ul>
<b>Directions</b>
<ul style="list-style-type: none"> <li>To start feed: Remove cover and discard seal from container up wipe corner, tear off first wipe for use. Twist next wipe to hole in the container cover. Pull through about one inch. Repeat needed and snap off at a 90° angle. Keep cap closed to preserve the entire wipe surface. Allow to dry.</li> <li>If hands are visibly soiled or contaminated, use first wipe to sanitize with a second wipe.</li> <li>Discard after single use.</li> <li>Ideal for hand sanitization when soap and water are not available.</li> </ul>
<b>Inactive Ingredients</b>
Water
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70% Isopropyl Alcohol  
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Tanjung Agas Industrial Estate  
Johor, Malaysia.  
Website: [www.tidynonwoven.com](http://www.tidynonwoven.com)  
E-mail: [nonwoven@tidy.net](mailto:nonwoven@tidy.net)



NDC:80576-101

## ANTI GERM

isopropyl alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80576-101
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80576-101-01	1 mL in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**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(80576-101)

Revised: 3/2021

Tidy Non-Woven SDN BHD