

**HAND SANITIZER- alcohol gel**  
**TFI Holdings, Inc.**

*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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**Gel Hand Sanitizer**

**Active Ingredient(s)**

Alcohol 70% v/v

**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.

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**

glycerin, hydrogen peroxide, water, trolamine, carbomer homopolymer, propylene glycol

# Package Label - Principal Display Panel

128 FL OZ (1 Gallon) NDC: 78476-002-01



# HAND SANITIZER

128 FL OZ (1 Gallon)

Drug Facts	
<b>Active ingredient</b>	<b>Purpose</b>
Alcohol 70% v/v	Antiseptic
<b>Uses</b>	
Hand Sanitizer to help reduce germs that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</b>	
- on 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. There may be signs of a allergic condition.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
- Place enough product on hands to cover all surfaces. Rub hands together until dry.	
- Supervise children as older 6 years of age when using this product to avoid swallowing.	
<b>Other information</b>	
- Store between 15-20C (59-68F)	
- Avoid freezing and excessive heat above 43C (104F)	
<b>Inactive ingredients</b> : glycerin, hydrogen peroxide, purified water, 1,6-hexandiamine, carbomer, propylene glycol	

W1 Holdings, Inc. POB # 519, Smithfield, UT 84335

NDC: 78-476-002-01

## HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78476-002(NDC:74837-002)
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78476-002-01	3785 mL in 1 JUG; Type 0: Not a Combination Product	07/20/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/20/2020	

**Labeler** - TFI Holdings, Inc. (080901451)

**Registrant** - Renowned Trading, LLC (114392114)

## Establishment

Name	Address	ID/FEI	Business Operations
TFI Holdings, Inc.		080901451	relabel(78476-002)

Revised: 8/2020

TFI Holdings, Inc.