

**HAND SANITIZER- alcohol solution**  
**TALENT LINK COMPANY LIMITED**

*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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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. 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 80% 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.

**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

glycerin, hydrogen peroxide, purified water USP

### Package Label - Principal Display Panel

60mL NDC: 75413-100-01



The label features a central circular logo with 'HAND SANITIZER' in an arc above 'HL' and a pair of hands below. To the left, two green checkmarks indicate 'ALCOHOL ANTISEPTIC 80% - TOPICAL SOLUTION' and 'NON-STERILE SOLUTION'. A stylized 'HL' logo is in the top right. At the bottom left, a hand-droplet icon is shown. The volume 'VOL: 2,1 FL. OZ (60 ML)' is printed at the bottom right.

<b>Drug Facts</b>	
<b>Active ingredient</b> Alcohol 80% v/v.....	<b>Purpose</b> Antiseptic
<b>Uses</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame</b>	
• <b>Do not use</b> • in children less than 2 months of age. • on open skin wounds.	
• <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
• <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
• <b>Keep out of reach of children.</b> 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 under 6 years of age when using this product to avoid swallowing.	
<b>Inactive ingredients</b> Glycerin, Hydrogen Peroxide, Purified water USP.	
<b>Other information</b> • Store between 15-30°C (59-86F) • Avoid freezing and excessive heat above 40°C (104F)	
<b>Question or comments?</b> 515-280-9999	

DISTRIBUTION BY: SONG HONG VN USA, INC.  
3409 SE 14TH ST, DES MOINES, IA 50320, USA  
EMAIL: MICHAELTA515@YAHOO.COM  
TEL: 515-280-9999  
MFG LOT NUMBER: 000220  
MFG DATE: 30/03/2020  
EXP DATE: 3 YEARS FROM THE MFG DATE




8 938532 105011

MADE IN VIETNAM

100mL NDC: 75413-100-02

✓ ALCOHOL ANTISEPTIC 80% - TOPICAL SOLUTION  
✓ NON-STERILE SOLUTION




VOL:  
3,5 FL. OZ (100 ML)

**Drug Facts**

<b>Active ingredient</b> Alcohol 80% v/v	<b>Purpose</b> Antiseptic
<b>Uses</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <i>For external use only. Flammable. Keep away from heat or flame</i>	
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MFG LOT NUMBER: 000220  
MFG DATE: 30/03/2020  
EXP DATE: 3 YEARS FROM THE MFG DATE

  
 8 1938532 1105011  
**MADE IN VIETNAM**

250mL NDC: 75413-100-03

✓ ALCOHOL ANTISEPTIC 80% - TOPICAL SOLUTION  
✓ NON-STERILE SOLUTION



VOL:  
9 FL. OZ (250 ML)

**Hand Sanitizer**

**Drug Facts**

<b>Active ingredient</b> Alcohol 80% v/v	<b>Purpose</b> Antiseptic
<b>Uses</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <i>For external use only. Flammable. Keep away from heat or flame</i>	
<ul style="list-style-type: none"> <li>• <b>Do not use</b></li> <li>• in children less than 2 months of age.</li> <li>• on open skin wounds.</li> </ul> <ul style="list-style-type: none"> <li>• <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</li> <li>• <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.</li> <li>• <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</li> </ul>	
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 8 1938532 1105011  
**MADE IN VIETNAM**

500mL NDC: 75413-100-04



1000mL NDC: 75413-100-05




60mL NDC: 75413-100-11

## Hand Sanitizer

<b>Drug Facts</b>	
<b>Active ingredient</b> Alcohol 80% v/v	<b>Purpose</b> Antiseptic
<b>Uses</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <i>For external use only. Flammable. Keep away from heat or flame</i>	
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**MADE IN VIETNAM**

<b>Drug Facts</b>	
<b>Active ingredient</b> Alcohol 80% v/v	<b>Purpose</b> Antiseptic
<b>Uses</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
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EMAIL: MICHAELTA515@YAHOO.COM      EXP DATE: 3 YEARS FROM THE MFG DATE  
TEL: 515-280-9999

**MADE IN VIETNAM**



8 938532 105011

NON-STERILE SOLUTION

VOL:  
2,1 FL. OZ (60 ML)

**Drug Facts**

<b>Active ingredient</b> Alcohol 80% v/v.....	<b>Purpose</b> Antiseptic
<b>Uses</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
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EXP DATE: 3 YEARS FROM THE MFG DATE

8 938532 105011

MADE IN VIETNAM

100mL NDC: 75413-100-12

NON-STERILE SOLUTION

VOL:  
3,5 FL. OZ (100 ML)

**Drug Facts**

<b>Active ingredient</b> Alcohol 80% v/v.....	<b>Purpose</b> Antiseptic
<b>Uses</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <i>For external use only. Flammable. Keep away from heat or flame</i>	
<ul style="list-style-type: none"> <li>• <b>Do not use</b></li> <li>• in children less than 2 months of age.</li> <li>• on open skin wounds.</li> </ul> <ul style="list-style-type: none"> <li>• <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</li> <li>• <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.</li> <li>• <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</li> </ul>	
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MFG DATE: 30/03/2020  
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8 938532 105011

MADE IN VIETNAM

250mL NDC:75413-100-13



### Hand Sanitizer

<b>Drug Facts</b>	
<b>Active ingredient</b> Alcohol 80% v/v	<b>Purpose</b> Antiseptic
<b>Uses</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <i>For external use only. Flammable. Keep away from heat or flame</i>	
<ul style="list-style-type: none"> <li>• <b>Do not use</b></li> <li>- in children less than 2 months of age.</li> <li>- on open skin wounds.</li> </ul> <ul style="list-style-type: none"> <li>• <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</li> <li>• <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.</li> <li>• <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</li> </ul>	
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<b>Other information</b> - Store between 15-30°C (59-86°F) - Avoid freezing and excessive heat above 40°C (104°F)	
<b>Question or comments?</b> 515-280-9999	

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EMAIL: MICHAELTA515@YAHOO.COM  
TEL: 515-280-9999

MFG LOT NUMBER: 000220  
MFG DATE: 30/03/2020  
EXP DATE: 3 years from the MFG DATE

8 938532 105011

**MADE IN VIETNAM**

500mL NDC: 75413-100-14



### Hand Sanitizer

<b>Drug Facts</b>	
<b>Active ingredient</b> Alcohol 80% v/v	<b>Purpose</b> Antiseptic
<b>Uses</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <i>For external use only. Flammable. Keep away from heat or flame</i>	
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<b>Question or comments?</b> 515-280-9999	

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EMAIL: MICHAELTA515@YAHOO.COM  
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MFG LOT NUMBER: 000220  
MFG DATE: 30/03/2020  
EXP DATE: 3 YEARS FROM THE MFG DATE

8 938532 105011

**MADE IN VIETNAM**

1000mL NDC: 75413-100-15



<b>Drug Facts</b>	
<b>Active ingredient</b> Alcohol 80% v/v.	<b>Purpose</b> Antiseptic
<b>Uses</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame</b>	
<ul style="list-style-type: none"> <li>• <b>Do not use</b></li> <li>• in children less than 2 months of age.</li> <li>• on open skin wounds.</li> <li>• <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</li> <li>• <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.</li> <li>• <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</li> </ul>	
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<b>Other information</b> • Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)	
<b>Question or comments?</b> 515-280-9999	
DISTRIBUTION BY: SONG HONG VN USA, INC.      MFG LOT NUMBER: 000220 3409 SE 14TH ST, DES MOINES, IA 50320, USA      MFG DATE: 30/03/2020 EMAIL: MICHAELTA15@YAHOO.COM      EXP DATE: 3 YEARS FROM THE MFG DATE TEL: 515-280-9999 <b>MADE IN VIETNAM</b>	
 8 938532 1105011	

## HAND SANITIZER

alcohol solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75413-100
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75413-100-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2020	
2	NDC:75413-100-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2020	
3	NDC:75413-100-03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2020	
4	NDC:75413-100-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2020	
5	NDC:75413-100-05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2020	
6	NDC:75413-100-11	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2020	

7	NDC:75413-100-12	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2020	
8	NDC:75413-100-13	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2020	
9	NDC:75413-100-14	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2020	
10	NDC:75413-100-15	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/06/2020	

**Labeler** - TALENT LINK COMPANY LIMITED (555543020)

**Registrant** - TALENT LINK COMPANY LIMITED (555543020)

## Establishment

Name	Address	ID/FEI	Business Operations
TALENT LINK COMPANY LIMITED		555543020	manufacture(75413-100)

Revised: 10/2020

TALENT LINK COMPANY LIMITED