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.

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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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





250mL NDC: 75413-100-03



Hand Sanitizer Drug Facts Active ingredient Purpose Antiseptic Uses 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 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. Inactive ingredients Glycerin, Hydrogen Peroxide, Purified water USP. Other information - Store between 15-30°C (59-86F) - Avoid freezing and excessive heat above 40°C (104F) Question or comments? 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 MADE IN VIETNAM EXP DATE: 3 years from the MFG DATE





Drug Facts	
Active ingredient	Purpose
Alcohol 80% v/v	Antiseptic

UsesHand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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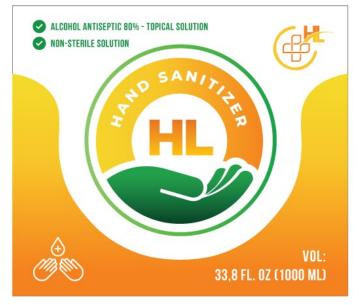
MFG LOT NUMBER: 000220 MFG DATE: 30/03/2020

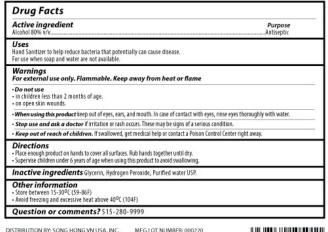
EXP DATE: 3 YEARS FROM THE MFG DATE



MADE IN VIETNAM

1000mL NDC: 75413-100-05





3409 SE 14TH ST, DES MOINES, IA 50320, USA EMAIL: MICHAELTAS15@YAHOO.COM TEL: 515-280-9999

MFG DATE: 30/03/2020 EXP DATE: 3 YEARS FROM THE MFG DATE

MADE IN VIETNAM





Drug Facts

Active ingredient

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MADE IN VIETNAM

Purpose Antiseptic

100mL NDC: 75413-100-12



Drug Facts

Active ingredient

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MEG LOT NUMBER: 000220

MFG DATE: 30/03/2020 EXP DATE: 3 YEARS FROM THE MFG DATE



MADE IN VIETNAM





500mL NDC: 75413-100-14



Hand Sanitizer Drug Facts Active ingredient Alcohol 80% v/v..... Purpose Antiseptic 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. 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 Inactive ingredients Glycerin, Hydrogen Peroxide, Purified water USP. Other information Store between 15-30°C (59-86F) Avoid freezing and excessive heat above 40°C (104F) Question or comments? 515-280-9999 DISTRIBUTION BY: SONG HONG VN USA, INC. 3409 SE 14TH ST, DES MOINES, IA 50320, USA EMAIL: MICHAELTA515@YAHOO.COM TFI: 515-280-9999 MFG LOT NUMBER: 000220 MFG DATE: 30/03/2020 MADE IN VIETNAM EXP DATE: 3 YEARS FROM THE MFG DATE



Drug Facts	
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MFG DATE: 30/03/2020 EXP DATE: 3 YEARS FROM THE MFG DATE

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HAND SANITIZER

alcohol solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75413-100	
Route of Administration	TOPICAL			

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

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6 A3C0 OX)	1.45 mL in 100 mL			
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL			
WATER (UNII: 059QF0KO0R)				

Pa	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