HAND SANITIZER- alcohol gel TRANG LY PHARMA TRADE 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

Antimicrobial

Use

Dry Hand Sanitizer helps prevent the development of bacteria on the skin.

It moisturizes and softens the hand skin with the sweet fragrance.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

• for children under 36 months.

Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.

For children: need to be supervised by adults when using it.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

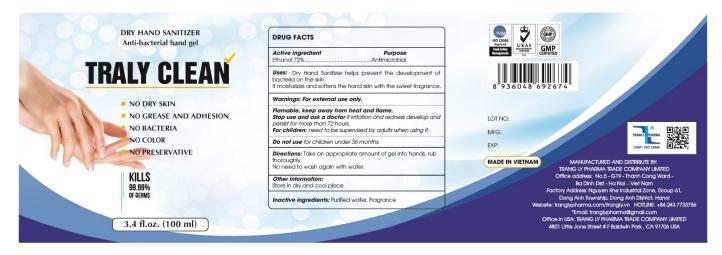
• Store in dry and cool place

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP Keep our of reach of children

Package Label - Principal Display Panel

100 mL NDC: 90098-100-01



250 mL NDC: 90098-100-02



500 mL NDC: 90098-100-03



kt 198x65

1000 mL NDC: 90098-100-04



2000 mL NDC: 90098-100-05



10000 mL NDC: 90098-100-06



kt 198x65

20000 mL NDC: 90098-100-07



kt 198x65

59 mL NDC: 90098-100-08



kt 198x65

1 Gallon NDC: 90098-100-09



kt 198x65

HAND SANITIZER

alcohol gel

Product Information	
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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:90098-100

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)
ALCOHOL (2 mL in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)	22 mL in 100 mL			
MINT (UNII: FV98Z8GITP)	6 mL in 100 mL			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
		100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		
2	NDC:90098-100- 02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		
3	NDC:90098-100- 03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		
4	NDC:90098-100- 04	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		
5	NDC:90098-100- 05	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		
6	NDC:90098-100- 06	10000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		
7	NDC:90098-100- 07	20000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		

8	NDC:90098-100- 08	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
9	NDC:90098-100- 09	20000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
Marketing Information				
	Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
_	TC monograph not fir	al part333A	03/30/2020	

Labeler - Trang Ly Pharma trade company limited (555252970)

Registrant - Trang Ly Pharma Trade Company Limited (555252970)

Establishment				
Name	Address	ID/FEI	Business Operations	
TRANG LY PHARMA TRADE COMPANY LIMITED		555252970	manufacture(90098-100)	

Revised: 10/2020 TRANG LY PHARMA TRADE COMPANY LIMITED