

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

DRY HAND SANITIZER
Anti-bacterial hand gel

TRALY CLEAN

- NO DRY SKIN
- NO GREASE AND ADHESION
- NO BACTERIA
- NO COLOR
- NO PRESERVATIVE

KILLS 99.99% OF GERMS

3.4 fl.oz. (100 ml)

DRUG FACTS	
Active ingredient Ethanol 72%.....	Purpose Antimicrobial
Uses: 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 and flame. 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.	
Do not use for children under 36 months.	
Directions: Take an appropriate amount of gel into hands, rub thoroughly. No need to wash again with water.	
Other information: Store in dry and cool place	
Inactive ingredients: Purified water, Fragrance	

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8 936048 692674

LOT NO:
MFG:
EXP:

MADE IN VIETNAM

MANUFACTURED AND DISTRIBUTE BY:
TRANG LY PHARMA TRADE COMPANY LIMITED
Office address: No.5 - G19 - Thanh Cong Ward - Ba Dinh Dist - Ha Noi - Viet Nam
Factory Address: Nguyen Khe Industrial Zone, Group 61, Dong Anh Township, Dong Anh District, Hanoi
Website: tranglypharma.com/trangly.vn HOTLINE: +84.243.7733756
*Email: tranglypharma@gmail.com
Office in USA: TRANG LY PHARMA TRADE COMPANY LIMITED
4801 Little Jone Street # F Baldwin Park, CA 91706 USA

250 mL NDC: 90098-100-02

DRY HAND SANITIZER
Anti-bacterial hand gel

TRALY CLEAN

- NO DRY SKIN
- NO GREASE AND ADHESION
- NO BACTERIA
- NO COLOR
- NO PRESERVATIVE

KILLS 99.99% OF GERMS

8.45 fl.oz. (250 ml)

DRUG FACTS	
Active ingredient Ethanol 72%.....	Purpose Antimicrobial
Uses: 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 and flame. 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.	
Do not use for children under 36 months.	
Directions: Take an appropriate amount of gel into hands, rub thoroughly. No need to wash again with water.	
Other information: Store in dry and cool place	
Inactive ingredients: Purified water, Fragrance	

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500 mL NDC: 90098-100-03

DRY HAND SANITIZER
Anti-bacterial hand gel

TRALY CLEAN

- NO DRY SKIN
- NO GREASE AND ADHESION
- NO BACTERIA
- NO COLOR
- NO PRESERVATIVE

KILLS 99.99% OF GERMS

16.9 fl.oz. (500 ml)

DRUG FACTS	
Active ingredient Ethanol 72%	Purpose Antimicrobial
Uses: 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 and flame. 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.	
Do not use for children under 36 months.	
Directions: Take an appropriate amount of gel into hands, rub thoroughly. No need to wash again with water.	
Other information: Store in dry and cool place	
Inactive ingredients: Purified water, Fragrance	

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kt 198x65

1000 mL NDC: 90098-100-04

DRY HAND SANITIZER
Anti-bacterial hand gel

TRALY CLEAN

- NO DRY SKIN
- NO GREASE AND ADHESION
- NO BACTERIA
- NO COLOR
- NO PRESERVATIVE

KILLS 99.99% OF GERMS

33.8 fl.oz. (1000 ml)

DRUG FACTS	
Active ingredient Ethanol 72%	Purpose Antimicrobial
Uses: 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 and flame. 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.	
Do not use for children under 36 months.	
Directions: Take an appropriate amount of gel into hands, rub thoroughly. No need to wash again with water.	
Other information: Store in dry and cool place	
Inactive ingredients: Purified water, Fragrance	

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2000 mL NDC: 90098-100-05

DRY HAND SANITIZER
Anti-bacterial hand gel

TRALY CLEAN

- NO DRY SKIN
- NO GREASE AND ADHESION
- NO BACTERIA
- NO COLOR
- NO PRESERVATIVE

KILLS 99.99% OF GERMS

67.6 fl.oz. (2000 ml)

DRUG FACTS	
Active ingredient Ethanol 72%	Purpose Antimicrobial
Uses: 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 and flame. 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.	
Do not use for children under 36 months.	
Directions: Take an appropriate amount of gel into hands, rub thoroughly. No need to wash again with water.	
Other information: Store in dry and cool place	
Inactive ingredients: Purified water, Fragrance	

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10000 mL NDC: 90098-100-06

DRY HAND SANITIZER
Anti-bacterial hand gel

TRALY CLEAN

- NO DRY SKIN
- NO GREASE AND ADHESION
- NO BACTERIA
- NO COLOR
- NO PRESERVATIVE

KILLS 99.99% OF GERMS

2.64 GAL (10L)

DRUG FACTS	
Active ingredient Ethanol 72%	Purpose Antimicrobial
Uses: 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 and flame. <i>Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.</i> <i>For children: need to be supervised by adults when using it.</i>	
Do not use for children under 36 months.	
Directions: Take an appropriate amount of gel into hands, rub thoroughly. No need to wash again with water.	
Other information: Store in dry and cool place	
Inactive ingredients: Purified water, Fragrance	

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kt 198x65

20000 mL NDC: 90098-100-07

DRY HAND SANITIZER
Anti-bacterial hand gel

TRALY CLEAN

- NO DRY SKIN
- NO GREASE AND ADHESION
- NO BACTERIA
- NO COLOR
- NO PRESERVATIVE

KILLS 99.99% OF GERMS

5.28 GAL (20L)

DRUG FACTS	
Active ingredient Ethanol 72%	Purpose Antimicrobial
Uses: 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 and flame. <i>Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.</i> <i>For children: need to be supervised by adults when using it.</i>	
Do not use for children under 36 months.	
Directions: Take an appropriate amount of gel into hands, rub thoroughly. No need to wash again with water.	
Other information: Store in dry and cool place	
Inactive ingredients: Purified water, Fragrance	

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59 mL NDC: 90098-100-08

DRY HAND SANITIZER
Anti-bacterial hand gel

TRALY CLEAN

- NO DRY SKIN
- NO GREASE AND ADHESION
- NO BACTERIA
- NO COLOR
- NO PRESERVATIVE

KILLS 99.99% OF GERMS

2 fl.oz. (59 ml)

DRUG FACTS	
Active ingredient Ethanol 72%	Purpose Antimicrobial
Uses: 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 and flame. <i>Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.</i> <i>For children: need to be supervised by adults when using it.</i>	
Do not use for children under 36 months.	
Directions: Take an appropriate amount of gel into hands, rub thoroughly. No need to wash again with water.	
Other information: Store in dry and cool place	
Inactive ingredients: Purified water, Fragrance	

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1 Gallon NDC: 90098-100-09

DRY HAND SANITIZER
Anti-bacterial hand gel

TRALY CLEAN

- NO DRY SKIN
- NO GREASE AND ADHESION
- NO BACTERIA
- NO COLOR
- NO PRESERVATIVE

KILLS 99.99% OF GERMS

1 GAL (3.785L)

DRUG FACTS	
Active Ingredient Ethanol 72%	Purpose Antimicrobial
Uses: 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 and flame. 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.	
Do not use for children under 36 months.	
Directions: Take an appropriate amount of gel into hands, rub thoroughly. No need to wash again with water.	
Other information: Store in dry and cool place	
Inactive ingredients: Purified water, Fragrance	

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kt 198x65

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:90098-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	72 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	22 mL in 100 mL
MINT (UNII: FV98Z8G1TP)	6 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:90098-100-01	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 Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - TRANG LY PHARMA TRADE COMPANY LIMITED (55252970)

Registrant - TRANG LY PHARMA TRADE COMPANY LIMITED (55252970)

Establishment

Name	Address	ID/FEI	Business Operations
TRANG LY PHARMA TRADE COMPANY LIMITED		55252970	manufacture(90098-100)

Revised: 10/2020

TRANG LY PHARMA TRADE COMPANY LIMITED