

HAND SANITIZER- alcohol gel

THINH PHAT - KOREA SX TM XNK PHARMACEUTICAL COSMETICS COMPANY

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 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

for hand washing to decrease bacteria on the skin.

recommended for repeated use.

Warnings

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

Do not use

- in the eyes
- in case of contact, rinse eyes thoroughly with water

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

- wet hands thoroughly with product
- briskly rub hands together until dry
- Supervise children under 6 years in the use of this product.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

auqa, propylene glycol, fragrance green tea, carbomer, triethanolamine, glycerin

Package Label - Principal Display Panel

70 mL NDC: 78819-101-01



100 mL NDC: 78819-101-02



High quality products of:
IMPORT EXPORT MANUFACTURING CO., LTD
THINH PHAT COSMETIC - KOREA
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 Tel: (+84) 27.2628.2345 - (+84) 27.2628.3456 - (+84) 27.2628.5678
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 Phone: (+84) 28.66.88.63.63
 Website: Thinhphatkorea.com.



Hotline:
(+84) 976.63.63.63

Mfg.Date:
 Exp.Date
 Lot No:

MADE IN VIETNAM



DISINFECTANT HAND WASH GEL
TAKE CARE OF HEALTH



ALCOHOL HAND GEL
HYGIENE - ANTI-BACTERIA - MOISTURIZER

Net: 3.4.fl.oz.(100ml)

Drug Facts	Purpose
Active ingredient Alcohol	70%

Uses • for handwashing to decrease bacteria on the skin
 • recommended for repeated use

Warnings
For external use only.

Flammable, keep away from heat and flame.

Do not use in the eyes. In case of contact, rinse eyes thoroughly with water.

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Direction • wet hands thoroughly with product • bristly rub hands together until dry • supervise children under 6 years in the use of the product.

Other information
 • may discolor certain fabrics

Inactive ingredients	Percentage
Alcohol	70.00%
Phorylene Glycol	0.84%
Fragrance Green Tea	0.3%
Carbomer	0.25%
Trehalulamine	0.3%
Glycerin	0.02%

Based on antibacterial efficiency testing results on 5 types of microorganisms (Salmonella typhi, Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Shigella flexner).
 Compliance with the hand washing procedure of The Vietnamese Ministry of Health.



8 9 3 8 5 2 5 1 3 8 5 4 7 5



250 mL NDC: 78819-101-03



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Mfg.Date:
 Exp.Date
 Lot No:

MADE IN VIETNAM



DISINFECTANT HAND WASH GEL
TAKE CARE OF HEALTH



ALCOHOL HAND GEL
HYGIENE - ANTI-BACTERIA - MOISTURIZER

Net: 8.5.fl.oz.(250ml)

Drug Facts	Purpose
Active ingredient Alcohol	70%

Uses • for handwashing to decrease bacteria on the skin
 • recommended for repeated use

Warnings
For external use only.

Flammable, keep away from heat and flame.

Do not use in the eyes. In case of contact, rinse eyes thoroughly with water.

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Direction • wet hands thoroughly with product • bristly rub hands together until dry • supervise children under 6 years in the use of the product.

Other information
 • store at the normal temperature
 • may discolor certain fabrics

Inactive ingredients	Percentage
Alcohol	70.00%
Phorylene Glycol	0.84%
Fragrance Green Tea	0.3%
Carbomer	0.25%
Trehalulamine	0.3%
Glycerin	0.02%

Based on antibacterial efficiency testing results on 5 types of microorganisms (Salmonella typhi, Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Shigella flexner).
 Compliance with the hand washing procedure of The Vietnamese Ministry of Health.



8 9 3 8 5 2 5 1 3 8 5 1 1 6



500 mL NDC: 78819-101-04



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 Website: Thinhphatkorea.com.



Mfg.Date:
 Exp.Date
 Lot No:

MADE IN VIETNAM

YEYU
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DISINFECTANT HAND WASH GEL
TAKE CARE OF HEALTH



ALCOHOL HAND GEL

HYGIENE - ANTI-BACTERIA - MOISTURIZER

Net: 17.fl.oz.(500ml)

Drug Facts	Purpose
Active ingredient Alcohol	70%
Uses • for handwashing to decrease bacteria on the skin • recommended for repeated use	
Warnings <i>For external use only.</i>	
Flammable, keep away from heat and flame.	
Do not use in the eyes. In case of contact, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Direction • wet hands thoroughly with product • briskly rub hands together until dry • supervise children under 6 years in the use of this product.	
Other information • store at the normal temperature • may discolor certain fabrics	
Inactive ingredients	
Alcohol	28.39%
Propylene Glycol	0.84%
Fragrance Green Tea	0.3%
Carbomer	0.25%
Triethanolamine	0.2%
Glycerin	0.02%

Based on antibacterial efficiency testing results on 5 types of microorganisms (Salmonella typhi, Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Stigella flexneri). Compliance with the hand washing procedure of The Vietnamese Ministry of Health.

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78819-101
Route of Administration	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
GLYCERIN (UNII: PDC6A3C0OX)	0.02 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.25 mL in 100 mL
WATER (UNII: 059QF0KO0R)	28.39 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.84 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.2 mL in 100 mL
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	0.3 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78819-101-01	70 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78819-101-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78819-101-03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78819-101-04	500 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 - THINH PHAT - KOREA SX TM XNK PHARMACEUTICAL COSMETICS COMPANY (557260987)

Registrant - THINH PHAT - KOREA SX TM XNK PHARMACEUTICAL COSMETICS COMPANY (557260987)

Establishment

Name	Address	ID/FEI	Business Operations
THINH PHAT - KOREA SX TM XNK PHARMACEUTICAL COSMETICS COMPANY		557260987	manufacture(78819-101)

Revised: 10/2020

THINH PHAT - KOREA SX TM XNK PHARMACEUTICAL COSMETICS COMPANY