

## **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.*

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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 70% v/v. Purpose: Antiseptic

#### **Purpose**

Antiseptic, Hand Sanitizer

#### **Use**

for handwashing 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 at the normal temperature
- may discolor certain fabrics

## Inactive ingredients

aqua, propylene glycol, fragrance apple, carbomer, triethanolamine, glycerin

## Package Label - Principal Display Panel

70ml NDC: 78819-100-01



100ml NDC: 78819-100-02



**High quality products of:**  
**IMPORT EXPORT MANUFACTURING CO., LTD**  
**THINH PHAT COSMETIC - KOREA**  
**Address:** No. 1599, Nhon Hoa 1 Hamlet, Duc Hoa Thuong Commune, Duc Hoa District, Long An Province, Viet Nam.  
**Tel:** (+84) 27.2628.2345 - (+84) 27.2628.3456 - (+84) 27.2628.5678  
**Website:** Thinhphatkorea.vn  
**Representative office:** No. 45, Street 48, Ward 16, District 8, Ho Chi Minh City, Viet Nam.  
**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)**

Active ingredient	Purpose
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	
Phenylene Glycol	0.30%
Fragrance Apple	0.3%
Carbomer	0.25%
Trehalulose	0.2%
Glycerin	0.02%

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



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



250ml NDC: 78819-100-03



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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)**

Active ingredient	Purpose
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 this product.

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

Inactive ingredients	
Alcohol	28.39%
Phenylene Glycol	0.34%
Fragrance Apple	0.3%
Carbomer	0.25%
Trehalulose	0.2%
Glycerin	0.02%

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



8 9 3 8 5 2 5 1 3 8 5 1 0 9



500ml NDC: 78819-100-04



High quality products of:  
**IMPORT EXPORT MANUFACTURING CO., LTD**  
**THINH PHAT COSMETIC - KOREA**  
 Address: No. 1599, Nhon Hoa 1 Hamlet, Duc Hoa Thuong  
 Commune, Duc Hoa District, Long An Province, Viet Nam.  
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 Ho Chi Minh City, Viet Nam.  
 Phone: (+84) 028.66.88.63.63  
 Website: Tinhphatkorea.com.



Mfg. Date:  
 Exp. Date  
 Lot No:

MADE IN VIETNAM

**YEYU**  
 star  
**DISINFECTANT HAND WASH GEL**  
 TAKE CARE OF HEALTH



ALCOHOL HAND GEL

HYGIENE - ANTI-BACTERIA - MOISTURIZER

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

Drug Facts	
Active ingredient	Purpose
Alcohol	70%
<b>Uses</b> • for handwashing to decrease bacteria on the skin • recommended for repeated use	
<b>Warnings</b> 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.	
<b>Direction</b> • wet hands thoroughly with product • briskly rub hands together until dry • supervise children under 6 years in the use of this product.	
<b>Other information</b> • store at the normal temperature • may discolor certain fabrics	
<b>Inactive ingredients</b>	
Alcohol	28.39%
Propylene Glycol	0.84%
Fragrance Apple	0.3%
Castor	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:788 19 -100
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
APPLE (UNII: B423VGH5S9)	0.3 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.02 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.25 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.2 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.84 mL in 100 mL
WATER (UNII: 059QF0K00R)	28.39 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:788 19 -100 -01	70 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:788 19 -100 -02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:788 19 -100 -03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:788 19 -100 -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(78819-100)

Revised: 10/2020

THINH PHAT - KOREA SX TM XNK PHARMACEUTICAL COSMETICS COMPANY