

## **HAND SANITIZER- alcohol liquid**

**Thomas Chemicals, LLC**

*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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### **FOREST NYMPH 70% Liquid Hand Sanitizer with Fresh Cut Grass scent.**

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**

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**

# Forest Nymph

## HAND SANITIZER

LIQUID FORM 70%

Clean and enticing, with notes that will remind you  
of an exotic forest.

Store in a cool dark area.



**Thomas Chemicals**

43 Dewitt Ave • Mattoon, IL 61938 • [thomaschemical.main@gmail.com](mailto:thomaschemical.main@gmail.com) • 217-246-4940

Drug Facts
Active Ingredients
Amount
Directions
Warnings
For external use only. Do not use.
Do not use:
• on children less than 2 years old
• on open skin wounds
When using this product:
• Stop use and ask a doctor if irritation occurs.
Keep out of reach of children.
Directions
• Pour enough product into your hands to cover all surfaces.
• Rub hands together for at least 20 seconds.
• Rinse hands with water and dry.
Other Information
• Store between 60°F and 80°F.
• Avoid contact with eyes.
• Inactive Ingredients

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Drug Facts	
Active Ingredient(s)	Purpose
Alcohol 70% v/v	Antiseptic
Use(s)	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings	
For external use only. Flammable. Keep away from heat or flame.	
Do not use	
<ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul>	
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	
<ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul>	
Other Information	
<ul style="list-style-type: none"><li>• Store between 15-30C(59-86F)</li><li>• Avoid freezing and excessive heat above 40C (104F)</li></ul>	
Inactive ingredients purified water, fragrance, glycerin, vitamin E, hydrogen peroxide	

3785 mL NDC: 76865-005-01

8 oz forest nymph

236 mL NDC:76865-005-04

## FOREST NYMPH

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8 oz

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 **Thomas Chemicals**

40 Davis Ave • Mattoon, IL 61938 • thomaschemical.maine@gmail.com • 217-244-1111

## 2 oz forest nymph

59 mL NDC:76865-005-05



# FOREST NYMPH

## HAND SANITIZER

LIQUID FORM 70%

Clean and enticing, with notes that will remind you of an exotic forest.

Store in a cool dark area.

2 oz

43 Dewitt Ave • Mattoon, IL 61938 • thomaschemical.main@gmail.com • 217-246-4940 • cornvalley.us

### **Drug Facts**

#### **Active Ingredient[s]**

Alcohol 70% v/v.....Antiseptic

#### **Purpose**

#### **Use[s]**

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

#### **Warnings**

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

#### **Do not use**

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#### **Directions**

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#### **Other Information**

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- Avoid Freezing and excessive heat above 40C (104F)

**Inactive Ingredients:** purified water, fragrance, glycerin, vitamin E, hydrogen peroxide



**HAND SANITIZER**

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76865-005
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)			1.45 mL in 100 mL	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL	
WATER (UNII: 059QF0KO0R)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			0.2 mL in 100 mL	
BENZYL SALICYLATE (UNII: WAO5MNK9TU)			0.69 mL in 100 mL	
CINNAMYL ALCOHOL (UNII: SS8YOP444F)			0.09 mL in 100 mL	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)			0.21 mL in 100 mL	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)			0.72 mL in 100 mL	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)			0.21 mL in 100 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76865-005-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2020	
2	NDC:76865-005-02	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2020	
3	NDC:76865-005-03	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2020	
4	NDC:76865-005-04	236 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/09/2020	
5	NDC:76865-005-05	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/09/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	07/09/2020	

**Labeler** - Thomas Chemicals, LLC (117504978)

**Registrant** - Jessica Tutt (117504978)

## Establishment

Name	Address	ID/FEI	Business Operations
Thomas Chemicals, LLC		117504978	manufacture(76865-005)