

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.

Liquid Hand sanitizer with cedarwood 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.

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

- 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


CEDAR WOOD

HAND SANITIZER

LIQUID FORM 70 %

Cozy and comforting, woody and warm. The aroma of cedar, mixed with notes of pine, will instantly soothe you.

Store in a cool dark area.

 **Thomas Chemicals**
43 Dewitt Ave • Mattoon, IL 61938 • thomaschemical.main@gmail.com • 217-246-4940

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	
• 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.	
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 purified water, Cedarwood essential oil, glycerin, vitamin E, hydrogen peroxide	



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Drug Facts
Active ingredient(s)
Alcohol 70%
(solv)
Health care professional should be consulted if used for more than 30 days.
Warnings
For external use only. Not for ingestion.
Do not use if you have a known allergy to any of the ingredients.
When using this product, avoid contact with eyes, nose, mouth, and skin.
Keep out of reach of children.
Directions
• Pour enough product into your hands to cover them.
• Rub hands together for at least 20 seconds.
• Other information
• Store in a cool, dark area.
• Avoid contact with eyes, nose, mouth, and skin.
• Active ingredient(s):



3785 mL NDC: 76865-010-01


8 oz cedar wood



CEDAR WOOD

HAND SANITIZER
LIQUID FORM 70 %

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Store in a cool dark area.

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8 oz



First Aid:
Other Ingredients:
Alcohol 70% v/v
(60%)
Instructions: Care personnel: hand rubs to help reduce bacteria that potentially can cause illness.
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, flush with water. If irritation or rash occurs. These may be signs of a severe allergic reaction. Stop use and ask a doctor if irritation or rash occurs. These may be signs of a severe allergic reaction.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center.
Precautions:
• Use 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 ingestion.
Other Information:
• Store between 15-30C (59-86F)
• Avoid freezing and excessive heat above 40C (104F)
Other Ingredients: purified water, Cedarwood essential oil, glycerin, ethanol 2%, lemon

CEDAR WOOD

HAND SANITIZER
LIQUID FORM 70%

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8 oz

236 mL NDC 76865-010-04

2 oz

59ml NDC:76865-010-05

Drug Facts

Active Ingredient[s]

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

- 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.

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 purified water, Cedarwood essential oil, glycerin, vitamin E, hydrogen peroxide



59mL NDC:76865-010-05



CEDARWOOD

HAND SANITIZER

LIQUID FORM 70 %

Cozy and comforting, woody and warm. The aroma of cedar, mixed with notes of pine, will instantly soothe you. Store in a cool dark area.

2 oz

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Drug Facts

Active Ingredient[s]

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

- 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.

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: purified water, Cedarwood essential oil, glycerin, vitamin E, hydrogen peroxide

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76865-010
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
JUNIPERUS VIRGINIANA OIL (UNII: PAD4FN7P2G)	4 mL in 100 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76865-010-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/12/2020	
2	NDC:76865-010-02	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/12/2020	
3	NDC:76865-010-03	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/12/2020	
4	NDC:76865-010-04	236 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/12/2020	
5	NDC:76865-010-05	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/12/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	06/17/2020	

Labeler - Thomas Chemicals, LLC (117504978)

Registrant - Jessica Tutt (117504978)

Establishment			
Name	Address	ID/FEI	Business Operations
Thomas Chemicals, LLC		117504978	manufacture(76865-010)

Revised: 8/2020

Thomas Chemicals, LLC