

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.

Strawberry scented 70 % hand sanitizer

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



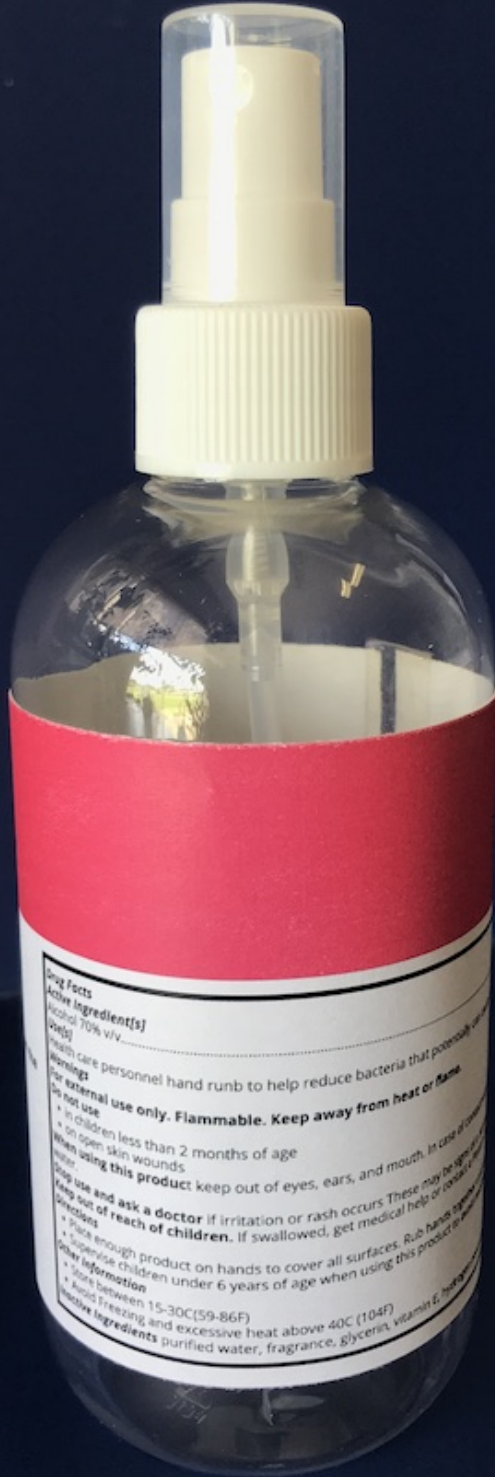
STRAWBERRY

HAND SANITIZER
LIQUID FORM 70%

The crisp scent of fresh picked Strawberries from the vine. Store in a cool dark area.

 **Thomas Chemicals**
40 Drexel Ave • Madison, IL 61105 • thomaschemicals@gmail.com • 708.246.4444

8 oz



Drug Facts

Active Ingredient(s)

Alcohol 70% v/v

Uses(s)

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

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.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of an allergic reaction. Stop use if rash persists.

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

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.

Other information

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

Inactive ingredients purified water, fragrance, glycerin, vitamin E, benzyl alcohol.

STRAWBERRY

HAND SANITIZER LIQUID FORM 70%

The crisp scent of fresh picked Strawberries from the vine. Store in a cool dark area.



43 Dewitt Ave • Matteson, IL 61938 • thomasmchemical.statin@gmail.com • 217-246-4940

8 oz

Drug Facts

Active Ingredient[s]

Alcohol 70% v/v

Purpose

Antiseptic

Use[s]

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

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Other Information

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

236 mL NDC: 76865-016-01

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76865-016
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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76865-016-01	236 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/24/2020	
2	NDC:76865-016-02	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/24/2020	
3	NDC:76865-016-03	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/24/2020	
	NDC:76865-016			

4	NDC:76865-016-04	3785 mL in 1 JUG; Type 0: Not a Combination Product	07/24/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part333A		07/24/2020	

Labeler - Thomas Chemicals, LLC (117504978)

Registrant - Jessica Tutt (117504978)

Establishment			
Name	Address	ID/FEI	Business Operations
Thomas Chemicals, LLC		117504978	manufacture(76865-016)

Revised: 7/2020

Thomas Chemicals, LLC