

HAND SANITIZER- alcohol liquid

Thomas Chemicals

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.

70 % Liquid Hand Sanitizer with Watermelon 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

WATERMELON


HAND SANITIZER

LIQUID FORM 70 %

The refreshing, mouth watering summer scent
of juicy watermelon.
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	
<ul style="list-style-type: none">• 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	
<ul style="list-style-type: none">• 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	
<ul style="list-style-type: none">• Store between 15-30C(59-86F)• Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients purified water, fragrance, glycerin, vitamin E, hydrogen peroxide	



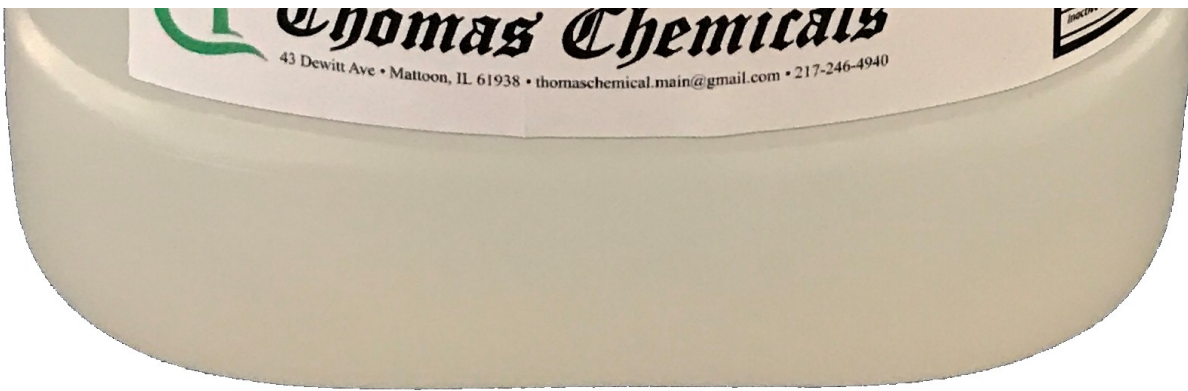
WATERMELON

HAND SANITIZER

LIQUID FORM 70%

The refreshing, mouth watering summer scent
of juicy watermelon.
Store in a cool dark area.

Drug Facts
Active Ingredient(s)
Alcohol 70% vol.
Use(s)
Health care personnel use this product to
Warnings
For external use only. Do not use if
Do not use
• In children less than 2 years of age
• On open skin wounds
When using this product use water to
Stop use and ask a doctor if irritation
Keep out of reach of children. For
Directions
• Place enough product on hands to
• Rub hands together for 20 seconds
Other Information
• Store between 55-80°F (13-27°C)
• Avoid freezing and thawing
• See Ingredients for other information



3785 mL NDC: 76865-006-01

8oz watermelon

236mL NDC:

watermelon 8oz

236 mL NDC:76865-006-04

SUMMERSCAPE

HAND SANITIZER LIQUID FORM 70%

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



8 OZ


Drug Facts	Purpose
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 <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• Store between 15-30C(59-86F)• Avoid Freezing and excessive heat above 40C (104F)	
Inactive Ingredients purified water, fragrance, glycerin, vitamin E, hydrogen peroxide	



WATERMELON

HAND SANITIZER
LIQUID FORM 70 %

The refreshing, mouth watering summer
scent of juicy watermelon.
Store in a cool dark area.

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8 OZ



Drug Facts

Active ingredient(s)

Alcohol 70% v/v

Water

Hydrogen peroxide

Other ingredients

Warnings

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

Do not use

• on children less than 2 months of age

• on open skin wounds

• on skin with irritation or rash

• on skin with a fever

• on skin with a rash

• on skin with a fever

• on skin with a rash

• on skin with a fever

• on skin with a rash

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• on skin with a fever

2 oz

59 mL NDC:76865-006-05



WATERMELON HAND SANITIZER

LIQUID FORM 70%

The refreshing, mouth watering summer scent of juicy watermelon.

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

- 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, fragrance, glycerin, vitamin E, hydrogen peroxide



HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76865-006
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
BENZYL BENZOATE (UNII: N863NB338G)	0.517 mL in 100 mL
LIMONENE, (+)- (UNII: GFD7C86Q1W)	0.2425 mL in 100 mL
VANILLIN (UNII: CHI530446X)	0.05 mL in 100 mL
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.2 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76865-006-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2020	
2	NDC:76865-006-02	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2020	
3	NDC:76865-006-03	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2020	
4	NDC:76865-006-04	236 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/09/2020	
5	NDC:76865-006-05	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 (117504978)

Registrant - Jessica Tutt (117504978)

Establishment			
Name	Address	ID/FEI	Business Operations
Thomas Chemicals, LLC		117504978	manufacture(76865-006)

Revised: 8/2020

Thomas Chemicals