

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.

Melon Berry scented Hand Sanitizer 70%

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

MELON BERRY

HAND SANITIZER

LIQUID FORM 70%

A fresh, fragrant melon, with top notes of fresh floral, muguet and berries. Heart notes of rose, jasmine and lavender.

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 rubs 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. There 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	



MELON BERRY


HAND SANITIZER

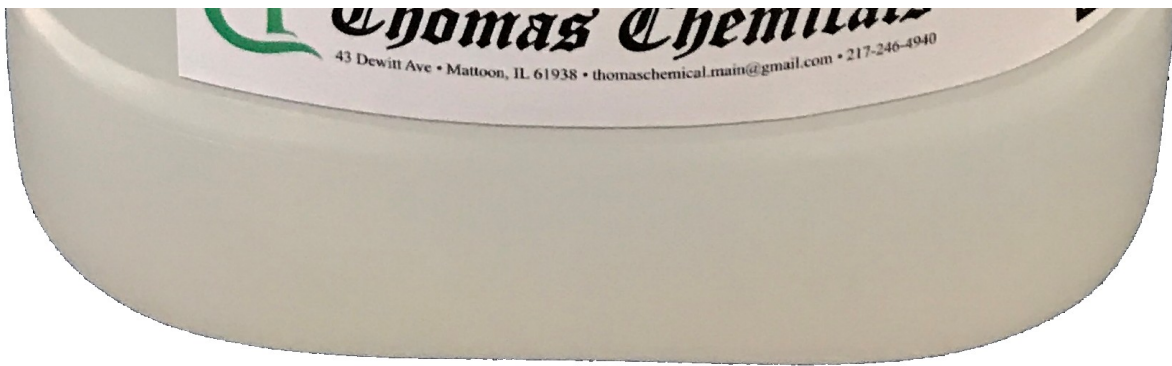
LIQUID FORM 70%

A fresh, fragrant melon, with top notes of fresh floral, muguet and berries. Heart notes of rose, jasmine and lavender.

Store in a cool dark area.

Drug Facts
Active Ingredients
Alcohol 70%
Other Ingredients
Fragrance
Warnings
For external use only.
Do not use
1. If irritation occurs, stop use and consult a healthcare professional.
2. Avoid contact with eyes.
3. Do not use if you are pregnant or breastfeeding.
4. Do not use if you are allergic to any of the ingredients.
Directions
• Apply a small amount to your hands.
• Rub your hands together for at least 20 seconds.
• Rinse your hands with water.
• Do not use if the product is expired.
• Do not use if the product is damaged.
• Do not use if the product is contaminated.

 **Dr. Organic**



3785 mL NDC: 76865-003-01

melon berry 8 oz

MELON BERRY

HAND SANITIZER
LIQUID FORM 70 %

A fresh, fragrant melon, with top notes of fresh floral,
muguet and berries. Heart notes of rose, jasmine and
lavender.

Store in a cool dark area.



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

8 OZ

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 ageon 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, Cedarwood essential oil, glycerin, vitamin E, hydrogen peroxide	




MELON BERRY

HAND SANITIZER
LIQUID FORM 70%

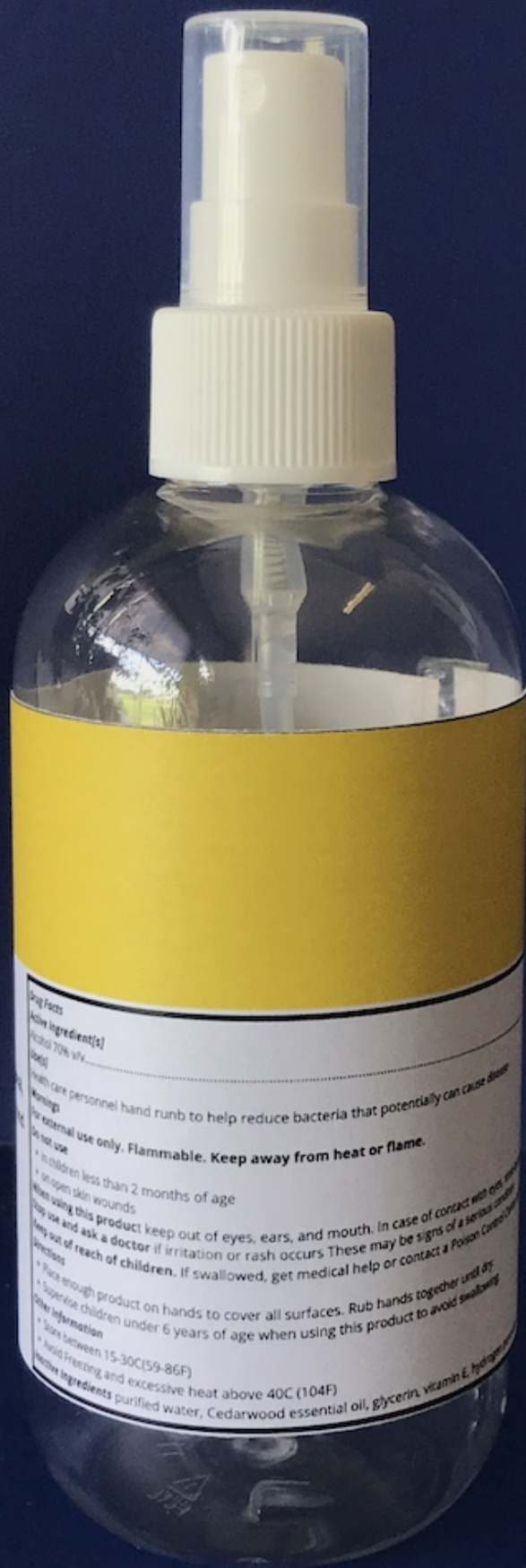
A fresh, fragrant melon, with top notes of fresh floral,
muguet and berries. Heart notes of rose, jasmine and
lavender.

Store in a cool dark area.

 **Thomas Chemicals**
40 Dorset Ave • Mattituck, IL 61878 • thomaschemicals.com • 217-246-4444

8 oz

Drug Facts
Active Ingredients
Alcohol (70%)
Directions
Wash hands thoroughly with water.
Apply a small amount of sanitizer to the palm of one hand.
Rub hands together, covering all surfaces of both hands.
Continue until hands are completely dry.
Do not use if you are allergic to any of the ingredients.
Keep out of reach of children.
Store in a cool, dark area.
Avoid contact with eyes.
If you experience any irritation, discontinue use.
For more information, visit thomaschemicals.com



235 mL NDC:76865-003-01

melon berry 2 oz



MELONBERRY

HAND SANITIZER

LIQUID FORM 70%

A fresh, fragrant melon, with top notes of fresh floral, muguet and berries. Heart notes of rose, jasmine and lavender. 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



59mL NDC:76865-003-05

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76865-003
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
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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76865-003-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2020	
2	NDC:76865-003-02	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2020	
3	NDC:76865-003-03	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2020	
4	NDC:76865-003-04	236 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/09/2020	
5	NDC:76865-003-05	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
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Thomas Chemicals, LLC		117504978	manufacture(76865-003)
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Revised: 8/2020

Thomas Chemicals, LLC