

## **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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### **Cucumber melon 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)

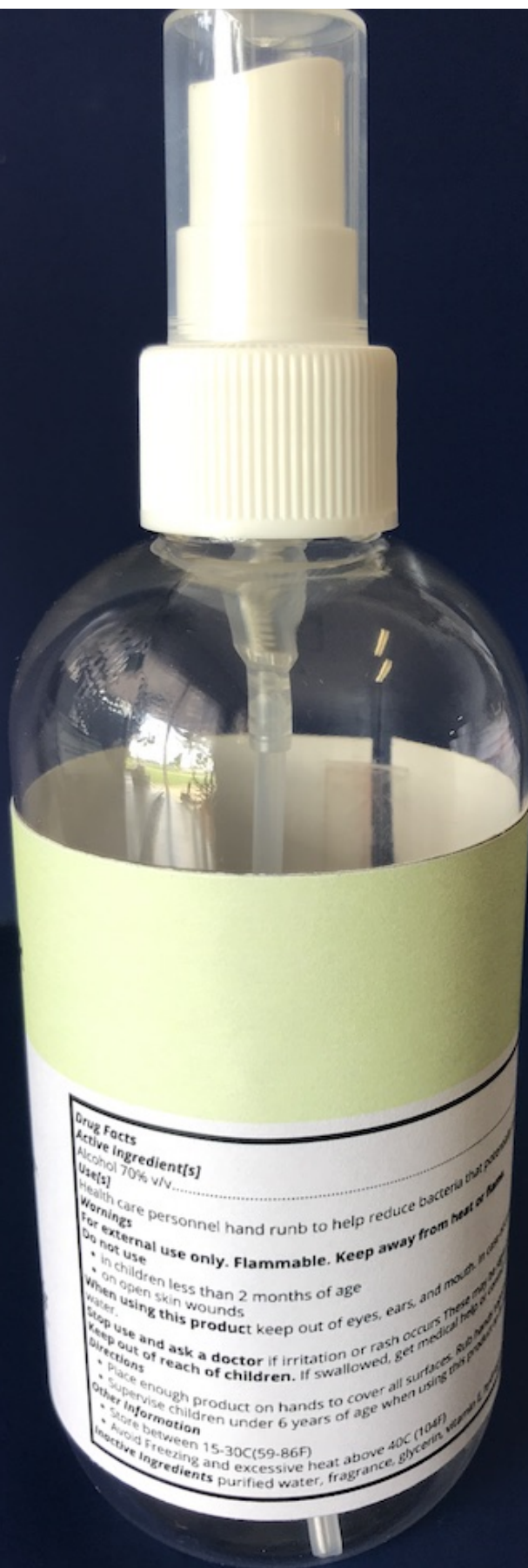
### Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

### Package Label - Principal Display Panel

236 mL NDC: 76865-018-01

|  |                |                   |                |   |            |  |  |  |  |   |  |   |  |   |  |   |  |  |  |   |  |
|--|----------------|-------------------|----------------|---|------------|--|--|--|--|---|--|---|--|---|--|---|--|--|--|---|--|
| <h1>CUCUMBER<br/>MELON</h1>  |                |                   |                |   |            |  |  |  |  |   |  |   |  |   |  |   |  |  |  |   |  |
| <b>HAND SANITIZER</b><br>LIQUID FORM 70%   |                |                   |                |   |            |  |  |  |  |   |  |   |  |   |  |   |  |  |  |   |  |
| A subtle blend of cucumber and honeydew.<br>Store in a cool dark area.   |                |                   |                |   |            |  |  |  |  |   |  |   |  |   |  |   |  |  |  |   |  |
| <br>43 Dewitt Ave • Matteson, IL 61938 • thomaschemical.maine@gmail.com • 217-246-4940  | <b>8 oz</b>    |                   |                |   |            |  |  |  |  |   |  |   |  |   |  |   |  |  |  |   |  |
| <table border="1"><tr><td><b>Drug Facts</b></td><td><b>Purpose</b></td></tr><tr><td><b>Active Ingredient[s]</b><br/>Alcohol 70% v/v.....</td><td>Antiseptic</td></tr><tr><td colspan="2"><b>Use[s]</b><br/>Health care personnel hand rub to help reduce bacteria that potentially can cause disease</td></tr><tr><td colspan="2"><b>Warnings</b><br/><b>For external use only. Flammable. Keep away from heat or flame.</b><br/><b>Do not use</b><ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul></td></tr><tr><td colspan="2"><b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</td></tr><tr><td colspan="2"><b>Stop use and ask a doctor</b> if irritation or rash occurs These may be signs of a serious condition</td></tr><tr><td colspan="2"><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</td></tr><tr><td colspan="2"><b>Directions</b><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></td></tr><tr><td colspan="2"><b>Other Information</b><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></td></tr><tr><td colspan="2"><b>Inactive Ingredients</b> purified water, fragrance, glycerin, vitamin E, hydrogen peroxide</td></tr></table> |                | <b>Drug Facts</b> | <b>Purpose</b> | <b>Active Ingredient[s]</b><br>Alcohol 70% v/v..... | Antiseptic | <b>Use[s]</b><br>Health care personnel hand rub to help reduce bacteria that potentially can cause disease |  | <b>Warnings</b><br><b>For external use only. Flammable. Keep away from heat or flame.</b><br><b>Do not use</b> <ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul> |  | <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. |  | <b>Stop use and ask a doctor</b> if irritation or rash occurs These may be signs of a serious condition |  | <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away. |  | <b>Directions</b> <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> |  | <b>Other Information</b> <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> |  | <b>Inactive Ingredients</b> purified water, fragrance, glycerin, vitamin E, hydrogen peroxide |  |
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| <b>Active Ingredient[s]</b><br>Alcohol 70% v/v.....  | Antiseptic     |                   |                |   |            |  |  |  |  |   |  |   |  |   |  |   |  |  |  |   |  |
| <b>Use[s]</b><br>Health care personnel hand rub to help reduce bacteria that potentially can cause disease   |                |                   |                |   |            |  |  |  |  |   |  |   |  |   |  |   |  |  |  |   |  |
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| <b>Inactive Ingredients</b> purified water, fragrance, glycerin, vitamin E, hydrogen peroxide  |                |                   |                |   |            |  |  |  |  |   |  |   |  |   |  |   |  |  |  |   |  |



**Drug Facts**

**Active Ingredient[s]**  
Alcohol 70% v/v

**Use[s]**

Health care personnel hand rub to help reduce bacteria that pass on germs.

**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 water.

**Stop use and ask a doctor** if irritation or rash occurs. These may be signs of an allergic reaction. If irritation or rash occurs, get medical help. Do not use if you have a known allergy to any of the ingredients.

**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.
- Store between 15-30C (59-86F)


**Other Information**

- Avoid freezing and excessive heat above 40C (104F)
- Inactive ingredients purified water, fragrance, glycerin, vitamin E, benzyl alcohol

# CUCUMBER MELON

HAND SANITIZER  
LIQUID FORM 70 %

A subtle blend of cucumber and honeydew.  
Store in a cool dark area.

 **Thomas Chemicals**  
41 Dorrville Ave • Madison, IL 61754 • thomaschemicalsinc@gmail.com • 217-246-4040

8 oz

2 oz

59mL NDC:76865-018-05



# CUCUMBER MELON

## HAND SANITIZER

LIQUID FORM 70%

A subtle blend of cucumber and honeydew. Store in a cool dark area.

2 oz

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

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**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:76865-018 |
| 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:76865-018-01 | 236 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 03/30/2020           |                    |
| 2 | NDC:76865-018-05 | 59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product  | 03/30/2020           |                    |

## Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A                                 | 03/30/2020           |                    |

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

**Registrant** - Jessica Tutt (117504978)

## Establishment

| Name                  | Address | ID/FEI    | Business Operations    |
|-----------------------|---------|-----------|------------------------|
| Thomas Chemicals, LLC |         | 117504978 | manufacture(76865-018) |