

**HAND SANITIZER- alcohol gel**  
**2nd Gen Productions, Inc.**

*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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**Mothers Hand Sanitizer - Citron**

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 80% 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

3785 ml NDC: 76634-0142-1

DIE LINE: 5.00" W x 5.00" H (PROVIDED)

**MOTHERS**

ADVANCED ANTI-BACTERIAL  
**Hand Sanitizer**  
Kills 99.99% of Germs  
Moisturizing Topical Solution Gel  
Alcohol Antiseptic 70%

70%

1 GAL. (3.785 L)  
**CITRON**

**MOTHERS**

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active Ingredients</b> Ethyl Alcohol 70% v/v	Antiseptic
<b>Uses</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat and flame.	
<b>Do not use</b> • in children less than 2 months of age • on open skin wounds	
<b>When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</b>	
<b>Stop use and ask doctor if irritation or rash occurs. These may be signs of a serious condition.</b>	
<b>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</b>	
<b>Directions</b> • 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.	
<b>Other Information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive Ingredients</b> glycerin, hydrogen peroxide, purified water USP, fragrance	

MANUFACTURED FOR:  
Mothers® Polishes • Waxes • Cleaners, Inc.  
5456 Industrial Drive, Huntington Beach, CA 92649  
1-714-891-3364 www.mothers.com Made in USA

PRODUCT NO. 00148

0 78175 00148 1

ADDRESS ETC PRINT

50% PROCESS BLACK

McLean Design  
925.944.9500  
Date: 06/04/20  
Client: Mothers Polishes Waxes Cleaners  
File: MO\_00148\_HandSan\_Gel\_Alc70\_1GAL\_Citron\_MECH\_060420  
ADD "MFG FOR:" TO ADDRESS LINE, ADD FRAGRANCE & ETHYL TO INGREDIENTS. ADD CITRUS

SPOTS  
MOTHERS RED PANTONE 186 C  
PROCESS BLACK  
PANTONE 396 C BRIGHT GREEN

PLEASE NOTE: PANTONE 186 C IS ONLY A "CLOSEST MATCH" FOR MOTHERS RED COLOR. PLEASE MATCH PREVIOUSLY APPROVED COLOR OR PROVIDED SAMPLE.

236 mL NDC: 76634-0142-8

MOTHERS

MOTHERS

ADVANCED ANTI-BACTERIAL

ADVANCED ANTI-BACTERIAL

# Hand Sanitizer

# Hand Sanitizer

Kills 99.99% of Germs

Moisturizing  
Topical Solution Gel

Alcohol Antiseptic 70%

70%

8 FL. OZ.  
(236 mL)



CITRON

### Drug Facts

Active Ingredients	Purpose
Ethyl Alcohol 70% v/v	Antiseptic

### Uses

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

### Warnings

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### Do not use

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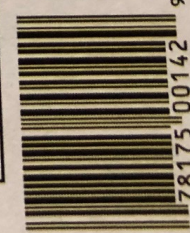
### Other Information

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

**Inactive Ingredients** glycerin, hydrogen peroxide, purified water USP, fragrance

MANUFACTURED FOR  
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PRODUCT NO. 00142



## HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76634-0142
<b>Route of Administration</b>	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
LEMON OIL (UNII: I9GRO824LL)	0.05 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.3 mL in 100 mL
EUCALYPTUS OIL (UNII: 2R04ONI662)	0.2 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.2 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL

<b>HYDROGEN PERO XIDE</b> (UNII: BBX060AN9V)	0.125 mL in 100 mL
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76634-0142-8	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:76634-0142-1	3785 mL in 1 BOTTLE, PLASTIC; 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** - 2nd Gen Productions, Inc. (038747564)

**Registrant** - 2nd Gen Productions, Inc. (038747564)

### Establishment

Name	Address	ID/FEI	Business Operations
2nd Gen Productions, Inc		038747564	manufacture(76634-0142)

Revised: 6/2020

2nd Gen Productions, Inc.