

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.

Corn Valley 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 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.

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





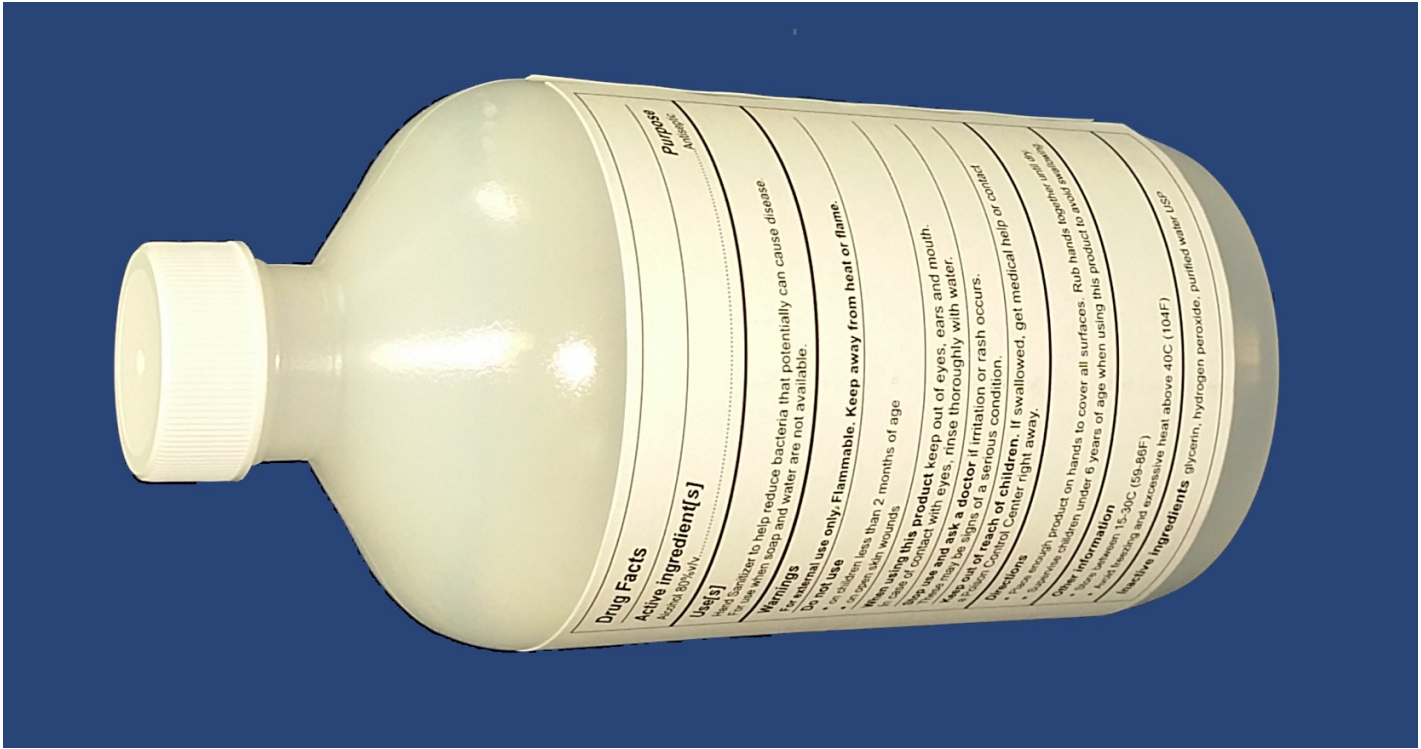
236mL NDC 76865-001-003

473mL NDC: 76865-001-01



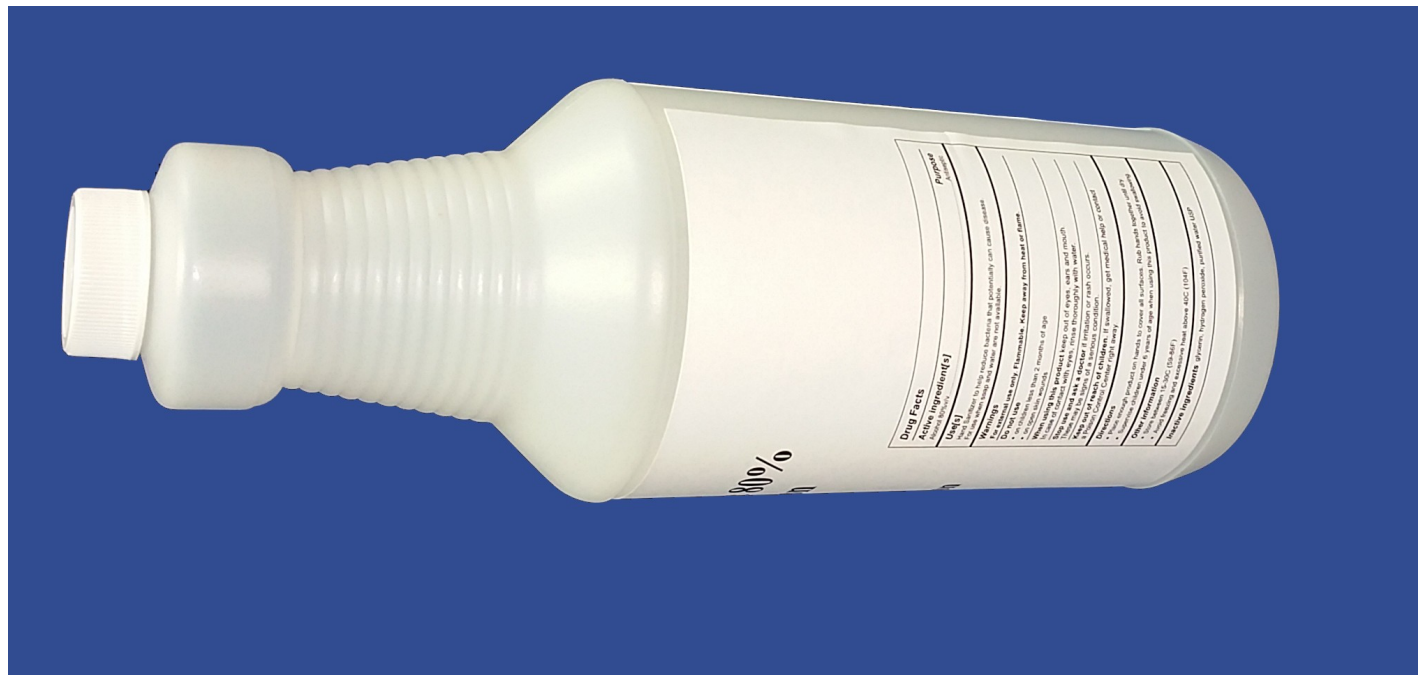


473mL NDC: 76865-001-02

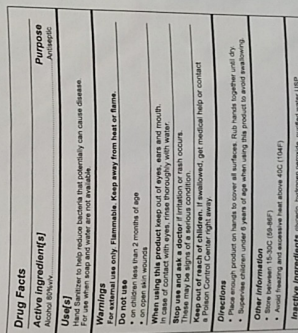




946mL NDC: 76865-001-04



3785mL NDC: 76865-001-05







10L NDC: 76865-001-06





20L NDC: 76865-001-07

Purpose	
Antiseptic	
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glycerin, hydrogen peroxide, purified water USP	



Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-sterile Solution

1040 L

Drug Facts
Active ingredient[s] Alcohol 80%/V.....
Use[s] Hand Sanitizer to help reduce germs. For use when soap and water are not available.
Warnings For external use only. Flammable.
Do not use <ul style="list-style-type: none">• on children less than 2 months old• on open skin wounds
When using this product In case of contact with eyes, flush with water for 15 minutes.
Stop use and ask a doctor These may be signs of an allergic reaction: <ul style="list-style-type: none">• hives• itching• swelling of the face or throat
Keep out of reach of children a Poison Control Center may be able to help.
Directions <ul style="list-style-type: none">• Place enough product on your palm to cover all surfaces of both hands.• Rub hands together until dry.
Other information <ul style="list-style-type: none">• Store between 15-30°C (59-86°F).• Avoid freezing and excessive heat.
Inactive ingredients



CORN VALLEY

HAND SANITIZER

Manufactured and
Distributed by:



Thomas Chemicals

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



1040L NDC: 76865-001-08



208L NDC: 76865-001-09



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Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80%v/v.....	Antiseptic
Use[s]	
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	
<ul style="list-style-type: none">• on 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 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 glycerin, hydrogen peroxide, purified water USP	

Alcohol Anti- Topical S

Hand San
Non-sterile



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Distributed by:

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HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76865-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76865-001-01	473 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/01/2020	
2	NDC:76865-001-02	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
3	NDC:76865-001-03	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
4	NDC:76865-001-04	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
5	NDC:76865-001-05	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
6	NDC:76865-001-06	10000 mL in 1 BAG; Type 0: Not a Combination Product	05/01/2020	
7	NDC:76865-001-07	20000 mL in 1 BAG; Type 0: Not a Combination Product	05/01/2020	
8	NDC:76865-001-08	1040000 mL in 1 TANK; Type 0: Not a Combination Product	05/01/2020	
9	NDC:76865-001-09	208000 mL in 1 DRUM; Type 0: Not a Combination Product	05/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/01/2020	

Labeler - Thomas Chemicals, LLC (117504978)

Registrant - Jessica Tutt (117504978)

Establishment

Name	Address	ID/FEI	Business Operations
Thomas Chemicals, LLC		117504978	manufacture(76865-001)

Revised: 4/2020

Thomas Chemicals, LLC