

## **ALCOHOL ANTISEPTIC TOPICAL SOLUTION- alcohol solution**

### **NCH Corporation**

*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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### **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.

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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**

9464ml; NDC Code 55533-524-02

<b>Alcohol Antiseptic 80% Topical Solution</b>	<b>Hand Sanitizer Non-Sterile Solution</b>
<b>Drug Facts</b> Active ingredient.....Purpose Alcohol 80% 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 or 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 eye 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 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)	
<b>Inactive ingredients</b> Glycerin, hydrogen peroxide, purified water USP	

See the Safety Data Sheet for more information.  
For medical or environmental emergencies, call CHEMTREC® at 1-800-424-9300.  
Not for Resale

Manufactured for:  
**MULTI-MIST Products**  
A Division of NCH Corporation  
1618 Northgate, Irving, Texas 75062  
NDC 55533-524-02

NET CONTENTS: 2.5 gallons / 9464 ml

0  
2  
5  
7  
  
M  
M  
B  
A  
  
2  
M  
0  
0  
5

208198 ml: NDC Code 55533-524-03

# Alcohol Antiseptic 80% Topical Solution

# Hand Sanitizer Non-Sterile Solution

<b>Drug Facts</b> Active ingredient ..... Purpose Alcohol 80% 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 or flame.
<b>Do not use</b> • in children less than 2 months of age • on open skin wounds
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eye thoroughly with water.
<b>Stop use and ask 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> • 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 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)
<b>Inactive ingredients</b> Glycerin, hydrogen peroxide, purified water USP

See the Safety Data Sheet for more information.  
For medical or environmental emergencies, call CHEMTREC® at 1-800-424-9300.  
Not for Resale

Manufactured for:  
**MULTI-MIST Products**  
A Division of NCH Corporation  
1618 Northgate, Irving, Texas 75062  
NDC 55533-524-03

NET CONTENTS: 55 gallons / 208198 ml

0  
2  
5  
7  
  
M  
M  
B  
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2  
M  
0  
0  
5

3785 ml NDC Code 55533-524-01

<b>Drug Facts</b> Active ingredient ..... Purpose Alcohol 80% 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 or flame.
<b>Do not use</b> • in children less than 2 months of age • on open skin wounds
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eye thoroughly with water.
<b>Stop use and ask 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. →

# Alcohol Antiseptic 80% Topical Solution

# Hand Sanitizer Non-Sterile Solution

Manufactured for:  
**MULTI-MIST Products** A Division of NCH Corporation  
1618 Northgate, Irving, Texas 75062

NET CONTENTS: 1 gallon/3785 mL

<b>Drugs Facts (continued)</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 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)
<b>Inactive ingredients</b> Glycerin, hydrogen peroxide, purified water USP

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See the Safety Data Sheet for more information.  
Not For Resale  
NDC 55533-524-01

0  
2  
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7  
  
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## ALCOHOL ANTISEPTIC TOPICAL SOLUTION

alcohol solution

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:55533-524

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:55533-524-01	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/15/2020	
2	NDC:55533-524-02	9464 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/15/2020	
3	NDC:55533-524-03	208198 mL in 1 DRUM; Type 0: Not a Combination Product	05/15/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/15/2020	

**Labeler** - NCH Corporation (126655562)

**Registrant** - NCH Corporation (008963910)

Revised: 5/2020

NCH Corporation