

**REPELWELL 80% ALCOHOL ANTISEPTIC- 80% ethyl alcohol hand sanitizer liquid**  
**Global Coating Solutions 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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**WHO 80% Ethyl Alcohol 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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### 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

### WHO 80% Alcohol Principal Display Panel

59mL NDC: 77136-300-02

<p><b>Drug Facts continued</b></p> <p><b>Directions</b></p> <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> <p><b>Other Information</b></p> <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> <p><b>Inactive Ingredients</b> glycerin, hydrogen peroxide, water</p>	<p><b>RepelWell™</b></p> <p><b>MAXIMUM STRENGTH</b></p> <p><b>Alcohol Antiseptic 80% Topical Solution</b></p> <p><b>LIQUID HAND SANITIZER</b> Not a Gel Dries Quick</p> <p><b>KILLS GERMS</b> Effective at Reducing Harmful Bacteria</p> <p><b>Exceeds CDC Recommendations</b></p> <p>NDC 78491-300-02 Made in the  <b>USA</b> Hand Sanitizer Non-Sterile Solution 2 fl.oz. (59ml)</p>	<p><b>Drug Facts</b></p> <table border="1"><thead><tr><th>Active Ingredient(s)</th><th>Purpose</th></tr></thead><tbody><tr><td>Alcohol 80% v/v.....</td><td>Antiseptic</td></tr></tbody></table> <p><b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> <p><b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame.</b></p> <p><b>Do not use</b></p> <ul style="list-style-type: none"><li>• on children less than 2 months of age</li><li>• on open skin wounds</li></ul> <p><b>When using this product</b> keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p><b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p>	Active Ingredient(s)	Purpose	Alcohol 80% v/v.....	Antiseptic
Active Ingredient(s)	Purpose					
Alcohol 80% v/v.....	Antiseptic					

236.5mL NDC: 77136-300-08

**RepelWell™**  
FIGHTS GERMS

● **MAXIMUM STRENGTH**

The CDC recommends using at least 60% alcohol to kill germs, viruses and bacteria. RepelWell exceeds this recommendation and meets WHO sanitizer requirements.

● **MADE IN THE USA**

RepelWell has partnered with an American manufacturer ensuring all manufacturing guidelines are being adhered to as well as timely production and delivery.

● **SANITIZES ON THE GO**

When soap and water are not available, stay protected with RepelWell Liquid Hand Sanitizer by keeping a bottle handy wherever you are.

**RepelWell™**

Distributed by:  
Global Coating Solutions, LLC  
1520 South 5th Street · Suite 304B  
ST. Charles, MO 63303 USA  
(636) 234-0025



**RepelWell™**

**MAXIMUM STRENGTH**

Alcohol Antiseptic 80% Topical Solution



NDC 78491-300-08  
Made in the **USA**  
Hand Sanitizer Non-Sterile Solution  
8 fl.oz. (236.5ml)

**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**

- 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 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**

glycerin, hydrogen peroxide, water

354.8ml NDC: 77136-300-12



**● MAXIMUM STRENGTH**

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**MAXIMUM STRENGTH**

Alcohol Antiseptic 80% Topical Solution



NDC 78491-300-12  
Made in the USA  
Hand Sanitizer Non-Sterile Solution  
12 fl.oz. (354.8ml)

**Drug Facts**

Active Ingredient(s)	Purpose
Alcohol 80% v/v.....	Antiseptic
<b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame.</b>	
<b>Do not use</b> • on 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 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> • 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, water	

709.7ml NDC: 77136-300-24



**● MAXIMUM STRENGTH**

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**● SANITIZES ON THE GO**

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**MAXIMUM STRENGTH**

Alcohol Antiseptic 80% Topical Solution



NDC 78491-300-24  
Made in the USA  
Hand Sanitizer Non-Sterile Solution  
24 fl.oz. (709.7ml)

**Drug Facts**

Active Ingredient(s)	Purpose
Alcohol 80% v/v.....	Antiseptic
<b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame.</b>	
<b>Do not use</b> • on 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 eyes thoroughly with water.	
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<b>Inactive Ingredients</b> glycerin, hydrogen peroxide, water	

**REPELWELL 80% ALCOHOL ANTISEPTIC**

80% ethyl alcohol hand sanitizer liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78491-300
<b>Route of Administration</b>	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:78491-300-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2020	
2	NDC:78491-300-08	236.5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2020	
3	NDC:78491-300-12	354.8 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2020	
4	NDC:78491-300-24	709.7 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/05/2020	

**Labeler** - Global Coating Solutions LLC (079548927)

Revised: 6/2020

Global Coating Solutions LLC