

## **ESSENTIAL HAND SANITIZER- alcohol solution**

### **Genesis Custom Chemical Blending**

*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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This is a hand rub manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Rub Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand rub 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 Rub

### **Use**

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

### **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

**Hand Sanitizer**

0.0887206 L (88.7206 mL) NDC: 75125-4000-1



## Essential Hand Sanitizer

Alcohol Antiseptic 80%  
Topical Solution

Antiseptic Hand Rub  
Non-sterile Solution

88.8 mL

NDC: 75125-4000-1



<b>Drug Facts</b>	
<b>Active ingredient[s]</b> Alcohol 80% v/v .....	<b>Purpose</b> Antiseptic
<b>Use[s]</b> Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame Do not use <ul style="list-style-type: none"> <li>• in children less than 2 months of age</li> <li>• on open skin wounds</li> </ul>	
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.	
<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> glycerin, hydrogen peroxide, purified water USP	

## Hand Sanitizer

0.236588 L (236.588 mL) NDC: 75125-4000-2



## Essential Hand Sanitizer

Alcohol Antiseptic 80%  
Topical Solution

Antiseptic Hand Rub  
Non-sterile Solution

236.8 mL

NDC: 75125-4000-2



<b>Drug Facts</b>	
<b>Active ingredient[s]</b> Alcohol 80% v/v .....	<b>Purpose</b> Antiseptic
<b>Use[s]</b> Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame Do not use <ul style="list-style-type: none"> <li>• in children less than 2 months of age</li> <li>• on open skin wounds</li> </ul>	
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.	
<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> glycerin, hydrogen peroxide, purified water USP	

## Hand Sanitizer

0.295735 L (295.735 mL) NDC: 75125-4000-3



## Essential Hand Sanitizer

Alcohol Antiseptic 80%

Topical Solution

Antiseptic Hand Rub

Non-sterile Solution

296 mL

NDC: 75125-4000-3



<b>Drug Facts</b>	
<b>Active ingredient[s]</b> Alcohol 80% v/v .....	<b>Purpose</b> .....Antiseptic
<b>Use[s]</b> Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame Do not use <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> glycerin, hydrogen peroxide, purified water USP	

## Hand Sanitizer

0.946353 L (946.353 mL) NDC: 75125-4000-4



# Essential Hand Sanitizer

Alcohol Antiseptic 80%

Topical Solution

Antiseptic Hand Rub

Non-sterile Solution

946.37 mL



NDC: 75125-4000-4

<b>Drug Facts</b>	
<b>Active ingredient[s]</b> Alcohol 80% v/v .....	<b>Purpose</b> Antiseptic
<b>Use[s]</b> Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame Do not use <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> glycerin, hydrogen peroxide, purified water USP	

## Hand Sanitizer

3.78541 L (3785.41 mL) NDC: 75125-4000-5



## Essential Hand Sanitizer

Alcohol Antiseptic 80%  
Topical Solution

Antiseptic Hand Rub  
Non-sterile Solution

3785.41 mL

NDC: 75125-4000-5



<b>Drug Facts</b>	
<b>Active ingredient[s]</b> Alcohol 80% v/v .....	<b>Purpose</b> .....Antiseptic
<b>Use[s]</b> Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame Do not use <ul style="list-style-type: none"> <li>• in children less than 2 months of age</li> <li>• on open skin wounds</li> </ul>	
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.	
<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> glycerin, hydrogen peroxide, purified water USP	

## Hand Sanitizer

18.9271 L (18927.1 mL) NDC: 75125-4000-6



## Essential Hand Sanitizer

Alcohol Antiseptic 80%  
Topical Solution

Antiseptic Hand Rub  
Non-sterile Solution

18927.1 mL

NDC: 75125-4000-6



### Drug Facts

#### Active ingredient[s]

Alcohol 80% v/v

#### Purpose

Antiseptic

#### Use[s]

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

#### 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.

#### 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

## Hand Sanitizer

208.198 L (208198 mL) NDC: 75125-4000-7





## Essential Hand Sanitizer

Alcohol Antiseptic 80%

Topical Solution

Antiseptic Hand Rub

Non-sterile Solution

208198 mL

NDC: 75125-4000-7



<b>Drug Facts</b>	
<b>Active ingredient[s]</b> Alcohol 80% v/v .....	<b>Purpose</b> Antiseptic
<b>Use[s]</b> Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame Do not use <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. 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.	
<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> glycerin, hydrogen peroxide, purified water USP	

## Hand Sanitizer

1040.98824 L (1040988.24 mL) NDC: 75125-4000-8



## Essential Hand Sanitizer

Alcohol Antiseptic 80%

Topical Solution

Antiseptic Hand Rub

Non-sterile Solution

1040988.24 mL

NDC: 75125-4000-8



<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Alcohol 80% v/v .....	Antiseptic
<b>Use[s]</b>	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame	
Do not use	
<ul style="list-style-type: none"> <li>• in children less than 2 months of age</li> <li>• on open skin wounds</li> </ul>	
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.	
<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> glycerin, hydrogen peroxide, purified water USP	

## Hand Sanitizer

1249.1858887 L (1249185.8887 mL) NDC: 75125-4000-9



## Essential Hand Sanitizer

Alcohol Antiseptic 80%

Topical Solution

Antiseptic Hand Rub

Non-sterile Solution

1249185.89 mL

NDC: 75125-4000-9



### Drug Facts

#### Active ingredient[s]

Alcohol 80% v/v

#### Purpose

Antiseptic

#### Use[s]

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

#### 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.

#### 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

## ESSENTIAL HAND SANITIZER

alcohol solution

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:75125-4000

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 L in 100 L

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 L in 100 L
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 L in 100 L
WATER (UNII: 059QF0KO0R)	18.425 L in 100 L

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75125-4000-1	0.088 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/13/2020	
2	NDC:75125-4000-2	0.2368 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/13/2020	
3	NDC:75125-4000-3	0.296 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/13/2020	
4	NDC:75125-4000-4	0.94637 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/13/2020	
5	NDC:75125-4000-5	3.78541 L in 1 JUG; Type 0: Not a Combination Product	04/13/2020	
6	NDC:75125-4000-6	18.9271 L in 1 PAIL; Type 0: Not a Combination Product	04/13/2020	
7	NDC:75125-4000-7	208.198 L in 1 DRUM; Type 0: Not a Combination Product	04/13/2020	
8	NDC:75125-4000-8	1040.98824 L in 1 TANK; Type 0: Not a Combination Product	04/13/2020	
9	NDC:75125-4000-9	1249.18589 L in 1 TANK; Type 0: Not a Combination Product	04/13/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/13/2020	

**Labeler** - Genesis Custom Chemical Blending (080744214)

**Registrant** - Genesis Custom Chemical Blending (080744214)

### Establishment

Name	Address	ID/FEI	Business Operations
Genesis Custom Chemical Blending		080744214	manufacture(75125-4000)

