

**HAND SANITIZER GEL- hand sanitizer gel gel  
EXCLAVE HOLDINGS 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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**Hand Sanitizer Gel**

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. Isopropyl Alcohol (75%, 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 70% 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**

Water, Denatonium Benzoate, Thickener, Glycerine, T-Butyl-Alcohol

**Package Label - Principal Display Panel**

118 ml NDC: 78461-0001-01

	<p><b>Drug Facts</b></p>			
	<table border="1"> <thead> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Ethyl Alcohol 70% (w/v)</td> <td>Antimicrobial</td> </tr> </tbody> </table>	Active ingredient	Purpose	Ethyl Alcohol 70% (w/v)
Active ingredient	Purpose			
Ethyl Alcohol 70% (w/v)	Antimicrobial			
	<p><b>Uses</b></p> <p>■ To help reduce bacteria on the skin that could cause disease ■ Recommended for repeated use</p>			
	<p><b>Warnings</b></p> <p>Flammable. Keep away from fire or flame.</p> <p>For external use only</p> <p>When using this product, do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.</p> <p>Stop use and ask as doctor if irritation or rash appears or lasts.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.</p>			
	<p><b>Directions</b></p> <p>■ Place enough product in your palm to thoroughly covers your hands</p> <p>■ Rub hands together briskly until dry</p> <p>■ Children under 6 years of age should be supervised when using this product</p>			
	<p><b>Other Information</b></p> <p>■ Do not store above 110°F(43°C)</p> <p>■ May discolor certain fabrics or surfaces</p>			
	<p><b>Inactive Ingredients</b></p> <p>Water, Denatonium Benzoate, Thickener, Glycerine, T-Butyl-Alcohol, Fragrance</p>			
<p><b>4 FL OZ (118ml)</b></p>	<p>DISTRIBUTED BY: EXCLAVE HOLDING INC. 1000 ZANE STREET, LOUISVILLE, KY 40210</p>			

148 ml NDC: 78461-0001-02



**Hand Sanitizer Gel**  
**Topical Solution**

**Quick Drying**

**Kills 99.9% of Germs**

**70% ALCOHOL**

**5 FL OZ (148ml)**

Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol 70% (w/v).....	Antimicrobial
<b>Uses</b> ■ To help reduce bacteria on the skin that could cause disease ■ Recommended for repeated use	
<b>Warnings</b>	
Flammable. Keep away from fire or flame.	
For external use only	
When using this product, do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.	
Stop use and ask as doctor if irritation or rash appears or lasts.	
Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.	
<b>Directions</b>	
■ Place enough product in your palm to thoroughly covers your hands	
■ Rub hands together briskly until dry	
■ Children under 6 years of age should be supervised when using this product	
<b>Other Information</b>	
■ Do not store above 110°F(43°C)	
■ May discolor certain fabrics or surfaces	
<b>Inactive Ingredients</b>	
Water, Denatonium Benzoate, Thickener, Glycerine, T-Butyl-Alcohol, Fragrance	

DISTRIBUTED BY:  
 EXCLAVE HOLDING INC.  
 1000 ZANE STREET, LOUISVILLE, KY 40210

237 ml NDC: 78461-0001-03



**Hand Sanitizer Gel**  
**Topical Solution**

**Quick Drying**

**Kills 99.9% of Germs**

**70% ALCOHOL**

**8 FL OZ (237ml)**

Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol 70% (w/v).....	Antimicrobial
<b>Uses</b> ■ To help reduce bacteria on the skin that could cause disease ■ Recommended for repeated use	
<b>Warnings</b>	
Flammable. Keep away from fire or flame.	
For external use only	
When using this product, do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.	
Stop use and ask as doctor if irritation or rash appears or lasts.	
Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.	
<b>Directions</b>	
■ Place enough product in your palm to thoroughly covers your hands	
■ Rub hands together briskly until dry	
■ Children under 6 years of age should be supervised when using this product	
<b>Other Information</b>	
■ Do not store above 110°F(43°C)	
■ May discolor certain fabrics or surfaces	
<b>Inactive Ingredients</b>	
Water, Denatonium Benzoate, Thickener, Glycerine, T-Butyl-Alcohol, Fragrance	

DISTRIBUTED BY:  
 EXCLAVE HOLDING INC.  
 1000 ZANE STREET, LOUISVILLE, KY 40210

3785 ml NDC: 78461-0001-04



**Hand Sanitizer Gel**  
**Topical Solution**

**Quick Drying**

**Kills 99.9% of Germs**

**70% ALCOHOL**

**1 GALLON**  
**128 FL OZ (3785ml)**

**DISTRIBUTED BY:**  
**EXCLAVE HOLDING INC.**  
**1000 ZANE STREET, LOUISVILLE, KY 40210**

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Ethyl Alcohol 70% (v/v).....	Antimicrobial
<b>Uses</b>	
■ To help reduce bacteria on the skin that could cause disease ■ Recommended for repeated use	
<b>Warnings</b>	
Flammable. Keep away from fire or flame.	
For external use only	
When using this product, do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.	
Stop use and ask as doctor if irritation or rash appears or lasts.	
Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.	
<b>Directions</b>	
■ Place enough product in your palm to thoroughly covers your hands	
■ Rub hands together briskly until dry	
■ Children under 6 years of age should be supervised when using this product	
<b>Other Information</b>	
■ Do not store above 110°F(43°C)	
■ May discolor certain fabrics or surfaces	
<b>Inactive Ingredients</b>	
Water, Denatonium Benzoate, Thickener, Glycerine, T-Butyl-Alcohol, Fragrance	

**HAND SANITIZER GEL**

hand sanitizer gel gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78461-0001
<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 70 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
GLYCERIN (UNII: PDC6A3C0OX)	

### Product Characteristics

Color	white (CLEAR COLORLESS)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78461-0001-1	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78461-0001-2	148 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78461-0001-3	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78461-0001-4	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** - EXCLAVE HOLDINGS INC. (117536775)

**Registrant** - JOHN SALSMAN (117536775)

### Establishment

Name	Address	ID/FEI	Business Operations
EXCLAVE HOLDINGS INC.		117536775	manufacture(78461-0001)

Revised: 11/2020

EXCLAVE HOLDINGS INC.