

ATTIS CLEAN- alcohol hand sanitizer liquid
Attis Healthcare 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.

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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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

3,785 mL NDC: 77623-001-01




Manufactured by **Clean|All**

Alcohol Antiseptic 80% | Topical Solution
Hand Sanitizer - Non-sterile Solution

1 US Gallon (3,785 ml)

Attis Healthcare

12540 Broadwell Rd, Ste 2104 Milton, GA 30004
www.attishealthcare.com | info@attisind.com

Drug Facts	
Active Ingredient[s] Alcohol 80% v/v.....	PurposeAntiseptic
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"> • 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 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, sterilized water	 8 60003 92640 6

9,463 mL NDC: 77623-001-02



Attis Clean

Hand Sanitizer

Manufactured by 

Alcohol Antiseptic 80% | Topical Solution
Hand Sanitizer - Non-sterile Solution

2.5 US Gallons (9,463 ml)

Attis Healthcare

12540 Broadwell Rd, Ste 2104 Milton, GA 30004
www.attishealthcare.com | info@attisind.com

18,927 mL NDC: 77623-001-03



Attis Clean

Hand Sanitizer


Manufactured by 


Alcohol Antiseptic 80% | Topical Solution
Hand Sanitizer - Non-sterile Solution

5 US Gallons (18,927 ml)

Attis Healthcare

12540 Broadwell Rd, Ste 2104 Milton, GA 30004
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Drug Facts	
Active Ingredient[s] Alcohol 80% v/v.....	Purpose 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"> 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 Poison Control Center right away.	
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Other Information <ul style="list-style-type: none"> Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) 	 <p>8 60003 92640 6</p>
Inactive Ingredients Glycerin, hydrogen peroxide, sterilized water	

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Active Ingredient[s] Alcohol 80% v/v.....	Purpose Antiseptic
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Inactive Ingredients Glycerin, hydrogen peroxide, sterilized water	



Attis Clean

Hand Sanitizer

Manufactured by 

Alcohol Antiseptic 80% | Topical Solution
Hand Sanitizer - Non-sterile Solution

275 US Gallons (1,040,988 ml)

Attis Healthcare

12540 Broadwell Rd, Ste 2104 Milton, GA 30004
 www.attishealthcare.com | info@attisind.com

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

- in children less than 2 months of age
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Other Information

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- Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients

Glycerin, hydrogen peroxide, sterilized water

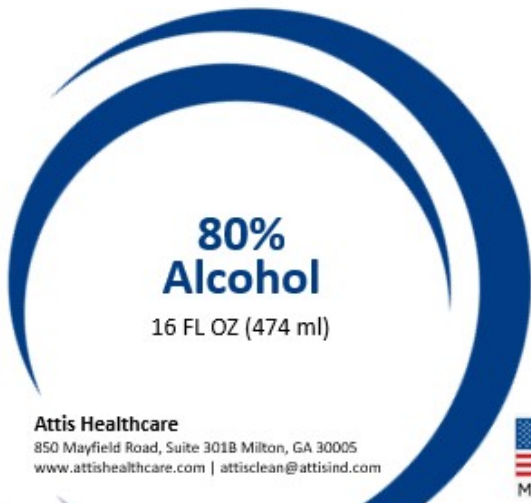


474 mL NDC 77623-001-05

Topical Solution | Antiseptic Hand Rub
 Non-sterile Solution



Hand Sanitizer



Attis Healthcare
 850 Mayfield Road, Suite 301B Milton, GA 30005
 www.attishealthcare.com | attisclean@attisind.com



Drug Facts

Active Ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic

Use[s]
 Healthcare 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.

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Other Information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, sterilized water

Manufactured in USA
 Clean All
 838 Erie Blvd West
 Syracuse, NY 13204

alcohol hand sanitizer liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77623-001
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
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77623-001-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77623-001-02	9463 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77623-001-03	18927 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:77623-001-04	1040988 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
5	NDC:77623-001-05	474 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Attis Healthcare Inc. (080365392)

Establishment

Name	Address	ID/FEI	Business Operations
Solvents and Petroleum Service, Inc.		117505240	manufacture(77623-001)