

## **HAND SANITIZER- isopropyl alcohol liquid**

**Adam's Polishes 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.*

-----

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)**

Isopropyl Alcohol 75% 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

glycerin, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel

118 ml NDC:74943-125-04

**ALCOHOL BASED**  
ISOPROPYL ALCOHOL ANTISEPTIC 75% • TOPICAL SOLUTION  
ANTISEPTIC HAND RUB • NON-STERILE SOLUTION

**ADAM'S POLISHES**

**HAND SANITIZER**

FAST ACTING ANTISEPTIC • UNSCENTED AND LEAVES HANDS SOFT AND SMOOTH

FORMULATED IN ACCORDANCE WITH  
**World Health Organization**  
RECOMMENDATIONS

MANUFACTURED AND BOTTLED IN AN  
**FDA**  
REGISTERED FACILITY IN THE U.S.A.

**AdamsPolishes.com**

**4 fl. oz (118)**

**Drug Facts**

Active ingredient	Purpose
Isopropyl Alcohol 75% v/v.....	Antiseptic

**Use[s]** 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.

**Manufactured by**  
B&B Blending, LLC, Northglenn, CO USA  
[www.bbblending.com](http://www.bbblending.com)

**Questions or Comments?** Call 1-866-965-0400  
Monday through Friday 8:00AM to 5:00PM MST.

8 10004 21353 1

237 mL NDC:74943-125-08

NDC 74943-125-08

**ALCOHOL BASED**

ISOPROPYL ALCOHOL ANTISEPTIC 75% • TOPICAL SOLUTION  
ANTISEPTIC HAND RUB • NON-STERILE SOLUTION

# HAND SANITIZER

FAST ACTING ANTISEPTIC • UNSCENTED AND LEAVES HANDS SOFT AND SMOOTH

FORMULATED IN ACCORDANCE WITH  
**World Health Organization**  
RECOMMENDATIONS

MANUFACTURED AND BOTTLED IN AN  
**FDA**  
REGISTERED FACILITY IN THE U.S.A.

[AdamsPolishes.com](http://AdamsPolishes.com)

**8 fl. oz (237 mL)**

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredient</b> Isopropyl Alcohol 75% 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.	
<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 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, purified water USP.	
<b>Manufactured by</b> B&B Blending, LLC, Northglenn, CO USA <a href="http://www.bbblending.com">www.bbblending.com</a>	
<b>Questions or Comments?</b> Call 1-866-965-0400 Monday through Friday 8:00AM to 5:00PM MST.	

8 10004 21352 4

473 mL NDC:74943-125-16

NDC 74943-125-16

**ALCOHOL BASED**

ISOPROPYL ALCOHOL ANTISEPTIC 75% • TOPICAL SOLUTION  
ANTISEPTIC HAND RUB • NON-STERILE SOLUTION

# HAND SANITIZER

FAST ACTING ANTISEPTIC • UNSCENTED AND LEAVES HANDS SOFT AND SMOOTH

FORMULATED IN ACCORDANCE WITH  
**World Health Organization**  
RECOMMENDATIONS

MANUFACTURED AND BOTTLED IN AN  
**FDA**  
REGISTERED FACILITY IN THE U.S.A.

[AdamsPolishes.com](http://AdamsPolishes.com)

**1 PINT / 16 fl. oz. (475 mL)**

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredient</b> Isopropyl Alcohol 75% v/v.....	Antiseptic
<b>Use[s]</b> 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.	
<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 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, purified water USP.	
<b>Manufactured by</b> B&B Blending, LLC, Northglenn, CO USA <a href="http://www.bbblending.com">www.bbblending.com</a>	
<b>Questions or Comments?</b> Call 1-866-965-0400 Monday through Friday 8:00AM to 5:00PM MST.	

8 10004 21354 8

946 mL NDC:74943-125-32



# ALCOHOL BASED HAND SANITIZER

NDC 74943-125-32  
**ALCOHOL BASED**  
ISOPROPYL ALCOHOL ANTISEPTIC 75% • TOPICAL SOLUTION  
ANTISEPTIC HAND RUB • NON-STERILE SOLUTION



## HAND SANITIZER

FAST ACTING ANTISEPTIC • UNSCENTED AND LEAVES HANDS SOFT AND SMOOTH

FORMULATED IN ACCORDANCE WITH  
**World Health  
Organization**  
RECOMMENDATIONS

MANUFACTURED AND BOTTLED IN AN  
**FDA**  
REGISTERED FACILITY IN THE U.S.A.



adamsPolishes.com

1 QUART / 32 fl. oz. (946 ml.)



### Drug Facts

**Active ingredient** Isopropyl Alcohol 75% v/v..... **Purpose** Antiseptic

**Use[s]** 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.

**Manufactured by**  
B&B Blending, LLC, Northglenn, CO USA  
www.bbblending.com

**Questions or Comments?** Call 1-866-965-0400  
Monday through Friday 8:00AM to 5:00PM MST.



8 10004 21356 2

3785 mL NDC:74943-125-28

## FRONT

NDC 74943-125-28  
**ALCOHOL  
BASED**

• ISOPROPYL ALCOHOL ANTISEPTIC 75%  
• TOPICAL SOLUTION  
• ANTISEPTIC HAND RUB  
• NON-STERILE SOLUTION



## HAND SANITIZER

FAST ACTING ANTISEPTIC • UNSCENTED AND LEAVES HANDS SOFT AND SMOOTH

FORMULATED IN ACCORDANCE WITH  
**World Health  
Organization**  
RECOMMENDATIONS

MANUFACTURED AND BOTTLED IN AN  
**FDA**  
REGISTERED FACILITY IN THE U.S.A.



adamsPolishes.com

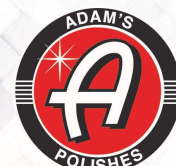
1 GALLON / 128 fl. oz. (3,785 ml.)



## REAR

**ALCOHOL  
BASED**

# HAND SANITIZER



**Drug Facts**

**Active ingredient** Isopropyl Alcohol 75% v/v..... **Purpose** Antiseptic

**Use[s]** 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.

**Manufactured by**  
B&B Blending, LLC, Northglenn, CO USA  
www.bbblending.com

**Questions or Comments?** Call 1-866-965-0400  
Monday through Friday 8:00AM to 5:00PM MST.



8 10004 21356 5

## HAND SANITIZER

isopropyl alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74943-125
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 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:74943-125-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74943-125-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74943-125-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74943-125-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:74943-125-28	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** - Adam's Polishes LLC (116803606)

**Registrant** - Adam's Polishes LLC (116803606)

Establishment			
Name	Address	ID/FEI	Business Operations
Adam's Polishes LLC		116803606	pack(74943-125) , label(74943-125)

**Establishment**

Name	Address	ID/FEI	Business Operations
B and B Blending LLC		609980792	manufacture(74943-125)

Revised: 4/2020

Adam's Polishes LLC