

**HAND SANITIZER- isopropyl alcohol liquid**  
**ALLIED PRESSROOM PRODUCTS**

*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 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.

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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

**Package Label - Principal Display Panel**

<b>Drug Facts</b>	
<b>Active ingredient[s]</b> Isopropyl Alcohol 75% v/v .....	<b>Purpose</b> Antiseptic
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<b>Inactive Ingredients</b> - Glycerin, Hydrogen Peroxide, Purified Water USP.	
<b>ALLIED PRESSROOM PRODUCTS</b> 4814 Persimmon Ct Monroe, NC 28110	800-327-8487 • info@alliedchem.com www.alliedpressroomproducts.com



The label features a circular logo at the top with the text "WORLD CLASS" and a stylized globe. Below the logo, the words "HAND" and "SANITIZER" are written in large, bold, black, block letters. A green horizontal bar contains the text "75% ALCOHOL TOPICAL SOLUTION - NON-STERILE". Below this bar, the text "Contains: 75% Isopropyl Alcohol & Emollients (Glycerin)." is displayed. Further down, a warning in bold states: "IF SOAP AND WATER ARE NOT READILY AVAILABLE, USE AN ALCOHOL-BASED HAND SANITIZER THAT CONTAINS AT LEAST 60% ALCOHOL. - Stated by the CDC". The NDC number "NDC 78851-222-02" and volume "118 mL." are listed below. At the bottom, there are two rectangular boxes labeled "BATCH #" and "EXPIRE ON:".

30 mL NDC78851-222-01

118 ml NDC 78851-222-02235 ml NDC 78851-222-03

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- Stated by the CDC

**NDC 78851-222-03**  
**235 mL.**

<b>BATCH #</b>	<b>EXPIRE ON:</b>
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946 ml NDC 78851-222-04

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**NDC 78851-222-04**  
**946 mL.**

<b>BATCH #</b>
<b>EXPIRE ON:</b>



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office: 800-327-8487 | info@alliedchem.com

IMPORTANT NOTICE - The following is made in lieu of all warranties, expressed or implied. Sellers only obligation shall be to replace such quantity of the product proved to be defective. Neither seller nor manufacturer shall be liable for any injury, loss or damage, direct, incidental or consequential arising out of the use or the inability to use this product. Before using, users shall determine the suitability of the product for their intended use, and user assumes all risk and liability whatsoever in connection therewith. The foregoing may not be altered except by an agreement signed by officers of seller and manufacturer.

3785 NDC 78851-222-05

BATCH #  
EXPIRE ON:

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NDC 78851-222-05  
3785 mL.

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NDC 78851-222-01  
30 mL.

BATCH # \_\_\_\_\_ EXPIRE ON: \_\_\_\_\_

## HAND SANITIZER

isopropyl alcohol liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78851-222
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:78851-222-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020	
2	NDC:78851-222-02	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020	
3	NDC:78851-222-03	235 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020	
4	NDC:78851-222-04	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020	
5	NDC:78851-222-05	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	06/18/2020	

**Labeler** - ALLIED PRESSROOM PRODUCTS (069895618)**Registrant** - ALLIED PRESSROOM PRODUCTS (069895618)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
ALLIED PRESSROOM PRODUCTS		069895618	manufacture(78851-222)