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.

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

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

Contains: 75% Isopropyl Alcohol & Emollients (Glycerin).

IF SOAP AND WATER ARE NOT READILY AVAILABLE, USE AN ALCOHOL-BASED HAND SANITIZER THAT CONTAINS AT LEAST 60% ALCOHOL. - Stated by the CDC

NDC 78851-222-02
118 mL.

BATCH #	EXPIRE ON:

30 mL NDC78851-222-01

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

Drug Facts

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WORLD CLASS

HAND SANITIZER

75% ALCOHOL TOPICAL SOLUTION – NON-STERILE

Contains: 75% Isopropyl Alcohol & Emollients (Glycerin).

IF SOAP AND WATER ARE NOT READILY AVAILABLE, USE AN ALCOHOL-BASED HAND SANITIZER THAT CONTAINS AT LEAST 60% ALCOHOL.
- Stated by the CDC

NDC 78851-222-03
235 mL.

BATCH #	EXPIRE ON:

946 ml NDC 78851-222-04

Drug Facts

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Isopropyl Alcohol 75% v/v .....Antiseptic

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WORLD CLASS

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- Stated by the CDC

NDC 78851-222-04
946 mL.

BATCH #
EXPIRE ON:

ALLIED PRESSROOM PRODUCTS
4814 Persimmon Ct Monroe, NC 28110
office: 800-327-8487 | info@alliedchem.com

3785 NDC 78851-222-05

Drug Facts
Active ingredient[s] ***Purpose*** Isopropyl Alcohol 75% v/v .....Antiseptic
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HAND SANITIZER

WORLD CLASS ALLIED PRESSROOM PRODUCTS

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- Stated by the CDC

NDC 78851-222-05
3785 mL.

BATCH #

EXPIRE ON:

ALLIED PRESSROOM PRODUCTS
4814 Persimmon Ct Monroe, NC 28110
office: 800-327-8487 | info@alliedchem.com

Drug Facts
Active ingredient[s] ***Purpose*** Isopropyl Alcohol 75% v/v .....Antiseptic
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- Stated by the CDC

NDC 78851-222-01
30 mL.

BATCH #	EXPIRE ON:

HAND SANITIZER

isopropyl alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78851-222
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: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

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

Labeler - ALLIED PRESSROOM PRODUCTS (069895618)

Registrant - ALLIED PRESSROOM PRODUCTS (069895618)

Establishment

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

Revised: 6/2020 ALLIED PRESSROOM PRODUCTS