HAND SANITIZER- alcohol liquid
Enter Labeler Name 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. 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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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)

Glycerin, Hydrogen Peroxide, Purified Water USP

Drug Facts

Active ingredient[s] ***Purpose***
Ethyl alcohol 80% v/v .....Antiseptic

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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

WORLD CLASS

HAND SANITIZER

80% ALCOHOL TOPICAL SOLUTION – NON-STERILE

Contains: 80% Ethyl 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 78851-111-03
235 mL.

BATCH #	EXPIRE ON:

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NDC 78851-111-02
118 mL.

BATCH #	EXPIRE ON:

118 ml NDC78851-111-02

30 ml NDC78851-111-01

235 ml NDC78851-111-03

946 ml NDC78851-111-04

3785 ml NDC78851-11-05

HAND SANITIZER

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78851-111
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
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:78851-111-01	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/09/2020	
2	NDC:78851-111-02	120 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/09/2020	
3	NDC:78851-111-03	236 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/09/2020	
4	NDC:78851-111-04	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/09/2020	
5	NDC:78851-111-05	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/09/2020	

Labeler - Enter Labeler Name ALLIED PRESSROOM PRODUCTS (069895618)

Registrant - ALLIED PRESSROOM PRODUCTS (069895618)

Establishment

Name	Address	ID/FEI	Business Operations
ALLIED PRESSROOM PRODUCTS		069895618	manufacture(78851-111)

Revised: 6/2020 Enter Labeler Name ALLIED PRESSROOM PRODUCTS