

HAND GEL SANITIZER- alcohol gel

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.

Hand Gel Isopropyl Alcohol Sanitizer

This is an isopropyl alcohol based hand sanitizer manufactured following the CDC recommendation of using an alcohol concentration of more than 60 % v/v alcohol when soap and water is not available.

It is manufactured by gelling a 70 % isopropyl alcohol solution with the minimum of an acrylate polymer to create a clear gel that is easy to apply and does not evaporate as readily as the liquid versions to provide sufficient dwell time to be effective.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product::

- a. Alcohol (isopropyl alcohol) (USP or Food Chemical Codex (FCC) grade) (70%, 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. Glycerin (1.00 % v/v)..
- c. Polypropylene Glycol (1.2 % v/v)..
- d. Acrylate Polymer (0.3% v/v).
- e. Sterile distilled water or boiled cold water.

No other materials are used.

Active Ingredient(s)

Isopropyl Alcohol 70% 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

Water, Polypropylene Glycol, glycerin, Acrylate polymer.

Package Label - Principal Display Panel

3785 ml NDC 78851-444-05

Drug Facts	
Active ingredient[s]	Purpose
Isopropyl alcohol 70% 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 • on open skin wounds	
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Inactive Ingredients - Water, Polyethylene Glycol, Glycerin, Acrylate Polymer.	



BATCH #
EXPIRE ON:



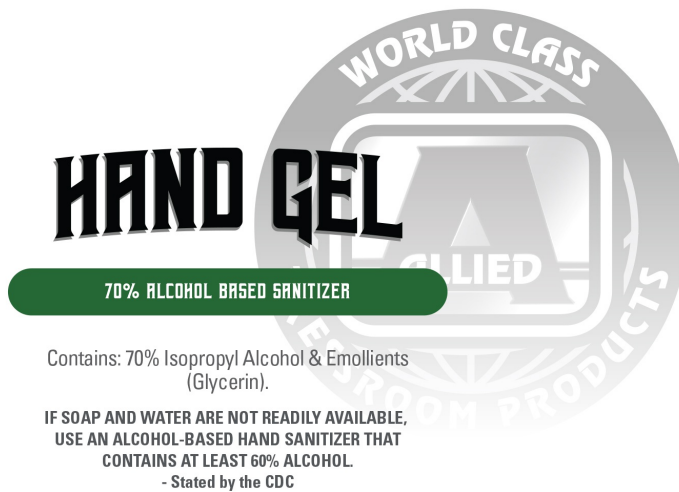
ALLIED PRESSROOM PRODUCTS
4814 Persimmon Ct Monroe, NC 28110
office: 800-327-8487 | info@alliedchem.com

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.

NDC 78851-444-05
3,785 mL

946 ml NDC 78851-444-04

Drug Facts	
Active ingredient[s] Isopropyl alcohol 70% 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 a 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 15-30°C (59-86°F). • Avoid freezing and excessive heat above 40°C (104°F). 	
Inactive Ingredients - Water, Polyethylene Glycol, Glycerin, Acrylate Polymer.	



BATCH #
EXPIRE ON:

Contains: 70% 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



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NDC 78851-444-04
946 mL.

240 ml NDC 78851-444-03

Drug Facts	
Active ingredient[s] Isopropyl alcohol 70% 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 a 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 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F) 	
Inactive Ingredients - Water, Polyethylene Glycol, Glycerin, Acrylate Polymer.	
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Contains: 70% 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 78851-444-03
240 mL.

BATCH # EXPIRE ON:

120 ml MDC 78851-444-02

Drug Facts	
Active ingredient[s] Isopropyl alcohol 70% 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 a 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 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F) 	
Inactive Ingredients - Water, Polyethylene Glycol, Glycerin, Acrylate Polymer.	
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70% ALCOHOL BASED SANITIZER

Contains: 70% 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 78851-444-02
120 mL.**

BATCH #	EXPIRE ON:
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105 ml NDC 78851-444-01 back

Drug Facts	
Active ingredient[s] Isopropyl alcohol 70% 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 a 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 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F) 	
Inactive Ingredients - Water, Polyethylene Glycol, Glycerin, Acrylate Polymer.	
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HAND GEL

70% ALCOHOL BASED SANITIZER

Contains: 70% 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 78851-444-01

105 mL.

BATCH #	EXPIRE ON:
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105 ml NDC 78851-444-01 front

105

HAND GEL SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78851-444
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	1.2 mL in 100 mL
ALLYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (LOW ALLYL METHACRYLATE) (UNII: P180E777XB)	0.3 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78851-444-01	105 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/23/2020	
2	NDC:78851-444-02	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/23/2020	
3	NDC:78851-444-03	240 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/23/2020	
4	NDC:78851-444-04	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/23/2020	
5	NDC:78851-444-05	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/23/2020	

Labeler - Allied Pressroom Products (069895618)**Registrant** - Allied Pressroom Products (069895618)**Establishment**

Name	Address	ID/FEI	Business Operations
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Revised: 6/2020

Allied Pressroom Products