

HAND SANITIZER A2- alcohol lotion
Global Impact Innovation 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. 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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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



1248 L NDC: 74588-533-03



1040 L NDC: 74588-533-03



 **GLOBAL
IMPACT
INNOVATION**

HAND SANITIZER A2

NON-STERILE SOLUTION

VOLUME: 1 GALLON

LOT # :

MFG Date:

NDC:74588-533-04

ETHYL ALCOHOL & IPA ANTISEPTIC 80%

TOPICAL SOLUTION

Drug Facts	Purpose
Active ingredient(s): Ethyl Alcohol & IPA 80% w/v	Antiseptic
Warnings	
Use as directed to help reduce bacteria that potentially can cause disease. Repeated use recommended.	
Directions	
• For external use only. Flammable. Keep away from heat or flame.	
• 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. There 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.	
Other information	
• Place enough product on hands to cover all surfaces. Rub hands together until dry.	
• Discontinue use if under 6 years of age when using this product to avoid swallowing.	
• Store between 15-30°C (59-86°F).	
• Avoid freezing and excursions from above 40°C (104°F).	
Contains ingredients: Ethanol, Hydrogen peroxide, Fossil Oil, Purified Water	
Works: 1100 SE Second Street Galva Henry IL 61434	
www.gi.io	

3.785 L NDC: 74588-533-04



18.927 L NDC: 74588-533-05

HAND SANITIZER A2			
alcohol lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74588-533
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	971.37414 L in 1248 L
Inactive Ingredients			
Ingredient Name		Strength	
GLYCERIN (UNII: PDC6A3C0OX)		18.6447 L in 1248 L	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)		1.86318 L in 1248 L	
WATER (UNII: 059QF0K00R)		193.10676 L in 1248 L	
ISOPROPYL ALCOHOL (UNII: ND2M416302)		44.83266 L in 1248 L	

FUSEL OIL (UNII: 2NK7O363Q6)

18.17856 L in 1248 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74588-533-03	1248 L in 1 TANK; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74588-533-02	1040 L in 1 TANK; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74588-533-04	3.785 L in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74588-533-05	18.927 L in 1 DRUM; 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 - Global Impact Innovation LLC (117465830)

Registrant - Global Impact Innovation LLC (117465830)

Establishment

Name	Address	ID/FEI	Business Operations
Global Impact Innovation LLC		117465830	manufacture(74588-533)

Revised: 4/2020

Global Impact Innovation LLC