

HAND SANITIZER B1- alcohol solution
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.

*Fermentation Alcohol

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.

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

- 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




**GLOBAL
IMPACT
INNOVATION**

HAND SANITIZER B1

NON-STERILE SOLUTION
VOLUME: 55 GALLONS

LOT #:
NDC: 74588-575-01

MFG Date:

ETHYL ALCOHOL & DENATONIUM BENZOATE ANTISEPTIC 80%

TOPICAL SOLUTION

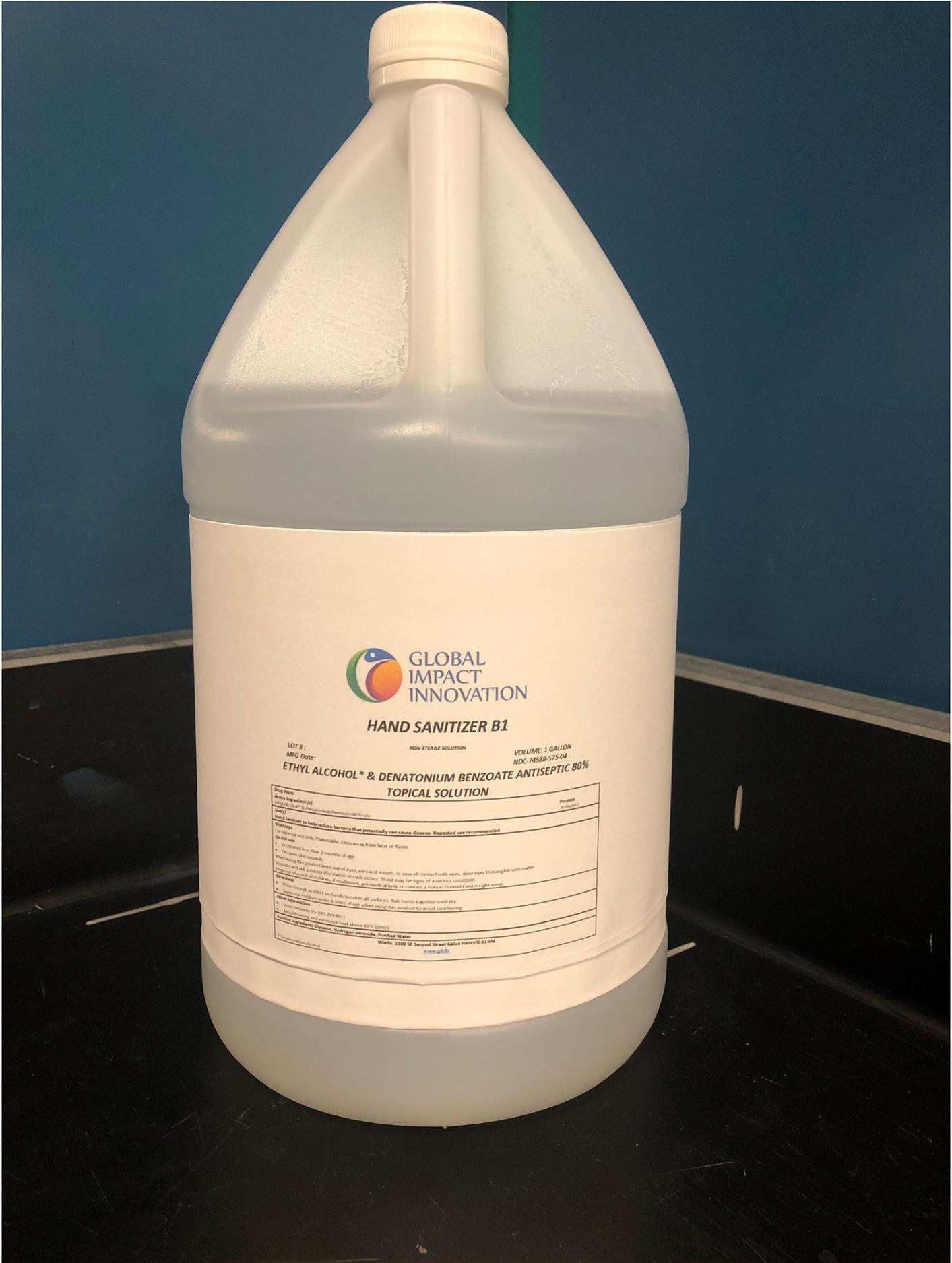
<small>Drug Name</small>	<small>Proprietary</small>
<small>Active Ingredient(s)</small>	<small>Proprietary</small>
<small>USDA National List # (if applicable) & Nomenclature (Proprietary 80% v/v)</small>	
<small>Uses</small>	
<small>Indications to help reduce bacteria that potentially can cause disease. Appropriate use recommended</small>	
<small>Warnings</small>	
<small>For external use only. Flammable. Keep away from heat or flame.</small>	
<small>Precautions</small>	
<ul style="list-style-type: none"> • Do not use on children less than 2 months of age. • Do not use after opening. 	
<small>When using this product keep out of eyes, nose and mouth. In case of contact with eyes, rinse eyes thoroughly with water. Stop use and seek advice of physician or eye-care provider. There may be signs of a serious condition.</small>	
<small>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</small>	
<small>Other</small>	
<small>When stored through the product on bench for cover all surfaces. Rub hands together until dry.</small>	
<small>Keep out of children's reach & out of sight when used. Use outside to avoid contamination.</small>	
<small>Other Information</small>	
<ul style="list-style-type: none"> • Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 30°C (86°F) 	
<small>Active Ingredient(s) Name(s), Strength(s) available, Purified Water</small>	
<small>Manufacturer Name</small>	<small>Website: 1-800-368-6868 (toll-free) Global Impact Innovation & IISB</small>
	<small>www.gi.io</small>

1H2/Y250/S/16
 USA/W4292

208 L NDC: 74588-575-01



1248 L NDC: 74588-575-03



**GLOBAL
IMPACT
INNOVATION**

HAND SANITIZER B1

LOT #: _____
MFG Date: _____

NON-STERILE SOLUTION

VOLUME: 1 GALLON
NDC-74588-575-04

**ETHYL ALCOHOL * & DENATONIUM BENZOATE ANTISEPTIC 80%
TOPICAL SOLUTION**

Drug Facts	Purpose
<p>Active ingredient(s): Ethyl Alcohol & Denatonium Benzoate 80% w/v</p> <p>Warnings: <ul style="list-style-type: none"> For external use only. Flammable. Keep away from heat or flame. In children less than 2 months of age. In eyes, also harmful. </p> <p>Directions: Use as directed. This product is for use on hands. In case of contact with eyes, rinse eyes thoroughly with water. If irritation or rash occurs, stop use and consult your physician. If symptoms persist, get medical help or contact a Poison Control Center or right away.</p> <p>Other information: Contains alcohol. Use with caution. Rub hands together until dry.</p> <p>Contains: Ethyl Alcohol (70-90% Ethanol) Denatonium Benzoate and water in alcohol solution</p> <p>Contains ingredients: Ethanol, Denatonium Benzoate, Purified Water</p> <p><small>© 2014 Global Impact Innovation</small></p>	<p>Hand Sanitizer</p>

3.785 L NDC: 74588-575-04



HAND SANITIZER B1

LOT #: _____ NON-STERILE SOLUTION VOLUME: 5 GALLONS
MFG Date: _____ NDC-74588-575-05
ETHYL ALCOHOL* & DENATONIUM BENZOATE ANTISEPTIC 80%
TOPICAL SOLUTION

Drug Facts	Purpose
Active ingredient(s): Ethyl Alcohol* & Denatonium Benzoate 80% v/v	Antiseptic
Uses: Hand Sanitizer to help reduce bacteria that potentially can cause disease. Repeated use recommended.	
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.	
Directions: • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Instruct children under 6 years of age when using this product to avoid swallowing.	
Other information: • Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)	
Inactive ingredients: Glycerin, Hydrogen peroxide, Purified Water	
*Fermentation Alcohol	
Works: 1100 SE Second Street Gaha Henry IL 61434 www.gilc.com	



HAND SANITIZER B1

NON-STERILE SOLUTION

LOT# :
MFG Date:

VOLUME: 1 Liter
NDC: 74588-575-06

ETHYL ALCOHOL* & Denatonium Benzoate 80%
TOPICAL SOLUTION



UN 1170

<p>Drug Facts Active ingredient [s]: Ethyl Alcohol* & Denatonium Benzoate 80% v/v Purpose Antiseptic</p>
<p>Use[s] Hand Sanitizer to help reduce bacteria that potentially can cause disease. Repeated use recommended.</p>
<p>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.</p>
<p>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. </p>
<p>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) </p>
<p>Inactive ingredients Glycerin, Hydrogen peroxide, Purified Water Address: 1100 SE Second Street Galva IL 61434 www.gii.llc</p>

*Fermentation Alcohol

Prevention:

P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

P233 Keep the container tightly closed.

P241 Use explosion-proof electrical/ventilating/lighting/ equipment.

P242 Use only non-sparking tools.

P243 Take precautionary measures against static discharge. P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/eye protection/ face protection.

Response:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337 + P313 If eye irritation persists: Get medical advice/attention.

Storage:

P403 + P235 Store in a well-ventilated place. Keep cool.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plan.

1 L NDC: 74588-575-06

HAND SANITIZER B1

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74588-575
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	166.4 L in 208 L

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	3.016 L in 208 L
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.26 L in 208 L
WATER (UNII: 059QF0K00R)	38.323308 L in 208 L
DENATONIUM BENZOATE ANHYDROUS (UNII: M5BA6GAF10)	0.00067 L in 208 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74588-575-01	208 L in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74588-575-03	1248 L in 1 TANK; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74588-575-04	3.785 L in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74588-575-05	18.927 L in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
5	NDC:74588-575-06	1 L in 1 BOTTLE; 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(74588-575)

Revised: 5/2020

Global Impact Innovation LLC