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.

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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)

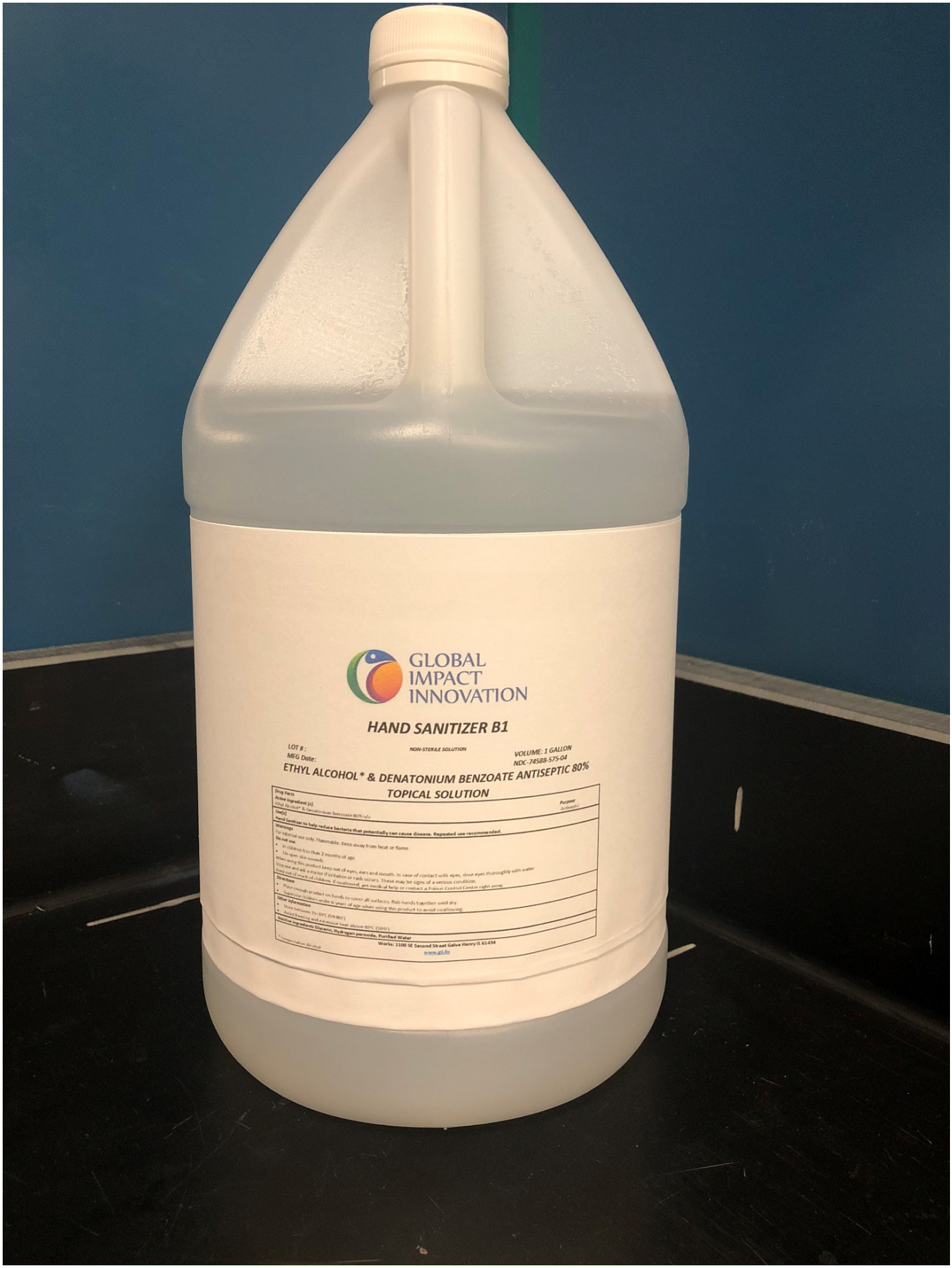
Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

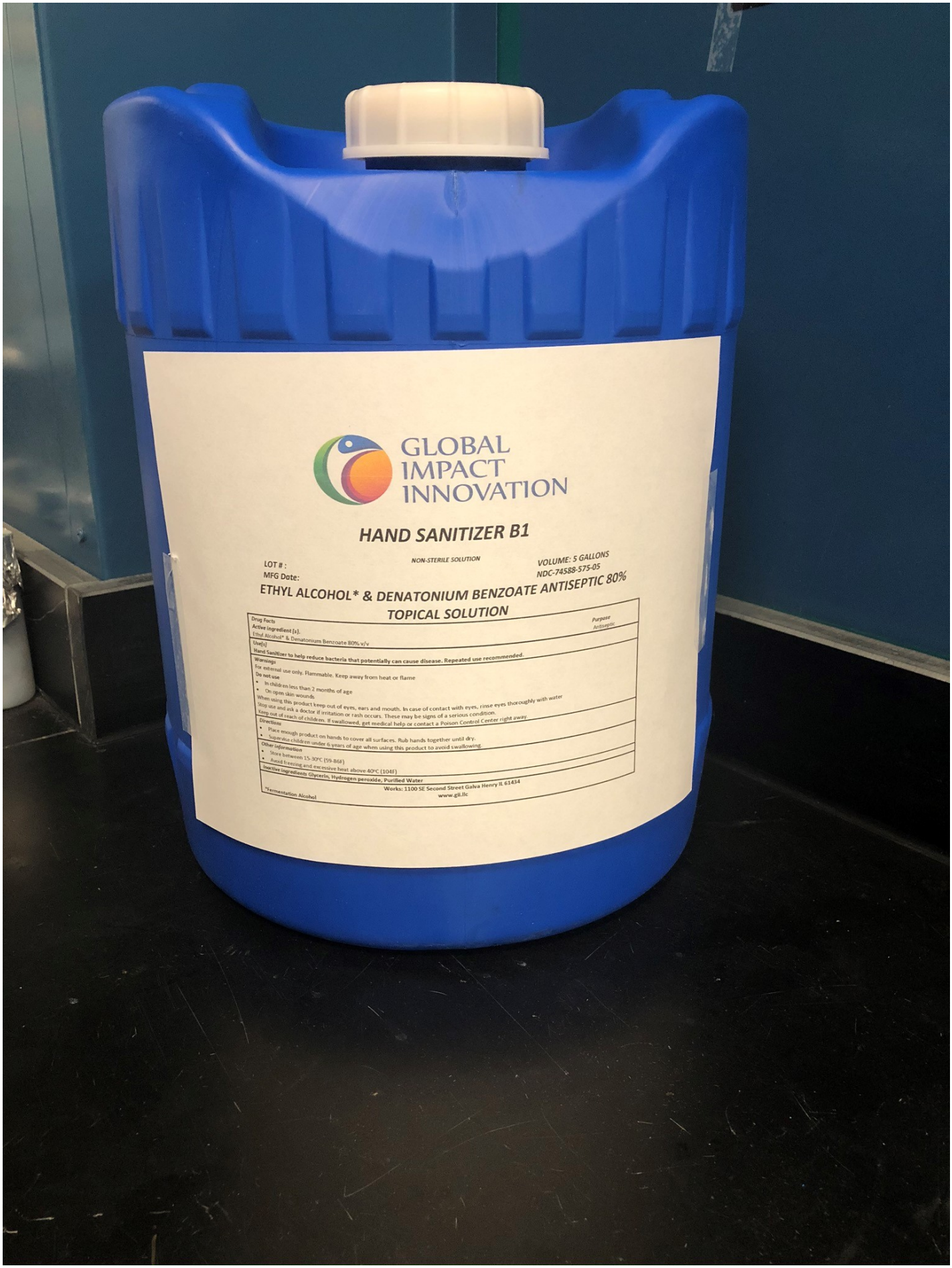
Package Label - Principal Display Panel

208 L NDC: 74588-575-01

1248 L NDC: 74588-575-03



3.785 L NDC: 74588-575-04



18.927 L NDC: 74588-575-05

GLOBAL IMPACT INNOVATION

HAND SANITIZER B1

NON-STERILE SOLUTION

LOT# : VOLUME: 1 Liter
MFG Date: NDC-74588-575-06

ETHYL ALCOHOL* & Denatonium Benzoate 80%

TOPICAL SOLUTION

Drug Facts

Active ingredient [s]:
Ethyl Alcohol* & Denatonium Benzoate 80% v/v

Purpose
Antiseptic

Use[s]
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.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30°C (59-86F)
- Avoid freezing and excessive heat above 40°C (104F)

Inactive ingredients **Glycerin, Hydrogen peroxide, Purified Water**

Address: 1100 SE Second Street Galva IL 61434
www.gii.llc

***Fermentation Alcohol**

UN 1170

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: 059QF0KO0R)	38.323308 L in 208 L
DENATONIUM BENZOATE ANHYDROUS (UNII: M5BA6GAF1O)	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