

**HYGIENEX HAND SANITIZER- 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**  
**HYGIENEX HAND SANITIZER**  
90% ETHANOL SOLUTION  
**ALCOHOL\* ANTISEPTIC 80%**  
TOPICAL SOLUTION

LOT# \_\_\_\_\_ MFG date: \_\_\_\_\_ VOLUME: 55 GALLONS

<p><b>Hazard Facts</b></p> <p><b>Active Ingredients:</b>        Alcohol* 80% v/v _____ Propyl _____        Antiseptic _____        Antimicrobial _____ and other non-volatile chemicals. For use on skin only. <b>Flammable. Keep away from heat or flame.</b></p> <p><b>Do not use:</b>        • on children less than 2 months of age        • on open skin wounds        • when using eye protectors</p> <p>• Keep out of eyes, ears and mouth. In case of contact with eyes, flush eyes thoroughly with water. Stop use and see a doctor if irritation or rash occurs. These may be signs of an allergic reaction.        • Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions:</b>        • Use enough product on hands to cover all surfaces. Rub hands together until dry.        • Do not use on children under the age of 6 years when using this product in animal enclosures.</p> <p><b>Warnings:</b>        • Avoid breathing in spray (10-15% OSHA 1910.104)        • Avoid contact with eyes, nose, mouth, skin, clothing, hair, or other surfaces.</p> <p><small>Contains Benzyl Alcohol, Benzyl Alcoholate, Benzyl Alcoholate, Purified Water, and other non-volatile chemicals.</small></p> <p style="text-align: center;"> <small>Manufactured by:</small>  <b>GLOBAL IMPACT INNOVATION, LLC</b>  <small>Address: 1500 10th Street, Suite 8, El Paso, TX 79902-3101        Phone: (915) 835-1100</small>  <b>MADE IN USA</b> </p>	<div style="text-align: center;">   <p><b>UN 1170</b></p> </div> <p><b>Prevention:</b>        P210 Keep away from heat/inflamable surfaces - No smoking        P223 Keep the container tightly closed        P231 Use explosion-proof electrical/ventilating/lighting equipment        P240 Use only non-sparking tools        P241 Take precautionary measures against static discharge        P244 Wash thoroughly after handling        P280 Wear protective gloves/eye protection/respiratory protection</p> <p><b>Response:</b>        P301 + P311 IF SWALLOWED: Call a doctor or hospital. Take of immediately all contaminated clothing. Rinse with water.        P302 + P352 IF ON SKIN: Wash thoroughly with water for several minutes. Remove contaminated clothing, if present, and keep it dry. Continue rinsing.        P303 + P361 + P353 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present, and keep to use. Continue rinsing.        P304 + P340 IF INHALED: Move to fresh air. Get medical attention if breathing is difficult.</p> <p><b>Storage:</b>        P201 + P202 Store in a well-ventilated place. Keep cool.        P233 Store in a well-ventilated place. Keep cool.        P240 Store in a well-ventilated place. Keep cool.        P241 Store in a well-ventilated place. Keep cool.        P280 Store in a well-ventilated place. Keep cool.        P301 Dispose of contents/container to an approved waste disposal plant.</p>
--	--

**9022-Enc**  
9022-Enc  
 Encapsulate Super  
 P73 140mg / per 10  
 This is processed by  
 NAH  
**E200**  
LOT#  
QUANTITY  
EXPIRATION DATE  
**03/31/2**  
03/31/2020

208 L NDC: 74588-570-01



GLOBAL  
INDUSTRIAL  
HYGIENEX  
HYGIENEX HAND SANITIZER  
ALCOHOL-BASED HAND SANITIZER  
FORMULA NUMBER: 1040 L NDC: 74588-570-02  
VOLUME: 1040 L (27.5 GAL)

**! H**  
UN 1170

MADE IN USA

1040 L NDC: 74588-570-02



1248 L NDC: 74588-570-03



3.785 L NDC: 74588-570-04



GLOBAL  
IMPACT  
INNOVATION  
**HYGIENEX HAND SANITIZER**  
ALCOHOL\* ANTISEPTIC 80%  
TOPICAL SOLUTION

Lot#      MFG date      VOLUME: 5 GALLONS

**Drug Facts**

**Active Ingredients**  
Alcohol\* Antiseptic 80%  
Purpose: Antiseptic

**Warnings**  
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**  
Wash hands thoroughly with water. Rub on and smooth. In case of contact with eyes, rinse eyes thoroughly with water. Rub on and smooth. Do not use on cuts or abrasions. Do not use on damaged skin.

**Other information**  
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**Contains**  
Alcohol\* Antiseptic 80%  
Contains: Alcohol\* Antiseptic 80%  
Contains: Alcohol\* Antiseptic 80%

**Manufactured by**  
GLOBAL IMPACT INNOVATION, LLC  
Address: 1305 W. Second Street, Suite 9, 60524  
Irvine, CA 92614  
949-260-0000  
**MADE IN USA**



UN 1170

**Precautions**  
P201 Keep away from heat/sunlight/open flames/hot surfaces - No smoking  
P231 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  
P284 Wash skin thoroughly after handling  
P300 Wear protective gloves/eye protection/face protection

**Response**  
P303 + P361 + P353 IF ON SKIN: Wash with soap and water.  
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P312 IF SWALLOWED: Get medical help or contact a Poison Control Center.

**Storage**  
P403 + P233 Store in a well-ventilated place. Keep cool.

**Disposal**  
P501 Dispose of contents/container to an approved waste disposal plant.

18.927 L NDC: 74588-570-05

# HYGIENEX HAND SANITIZER

alcohol solution

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74588-570
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	3.016 L in 208 L
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.26 L in 208 L
WATER (UNII: 059QF0KO0R)	38.324 L in 208 L

## Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:74588-570-01	208 L in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74588-570-02	1040 L in 1 TANK; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74588-570-03	1240 L in 1 TANK; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74588-570-04	3.785 L in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:74588-570-05	18.927 L in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	03/30/2020	

**Labeler** - Global Impact Innovation LLC (117465830)

Revised: 5/2020

Global Impact Innovation LLC