

HYGENIZE ORIGINAL HAND SANITIZER- isopropyl alcohol spray

HYGENIZE ORIGINAL HAND SANITIZER- alcohol gel

HYGENIZE ALCOHOL WIPES- alcohol patch

Hygenize Corp.

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. Isopropyl Alcohol (75%, 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)

Isopropyl Alcohol 75% 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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

HYGENIZE

MULTI-PURPOSE ANTIBACTERIAL WIPES

PPE  **Hygiene on a higher level**

Skin Friendly
Cleansing Formula
Non-Drip & Tear Resistant
Thick Non-Woven Fabric
160 Alcohol Wipes

  

Made in the USA 

6in. X 6.75in (15.24 cm x 17.145 cm)



Distributed by:
Hygenize Corp.
Los Angeles, CA
www.hygenize.com
(888) 494-3693

SAMPLE BARCODE

Drug Facts	
Active Ingredients Ethyl Alcohol 75% v/v.....	Purpose Antimicrobial
Uses - Sanitizing wipes to help reduce bacteria that can potentially cause disease	
Warnings - For external use only, Flammable, Keep away from heat or flame. Store below 105 F (41 C)	
Do not use <input type="checkbox"/> On children less than 2 months of age. <input type="checkbox"/> On broken skin.	
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	
When using this product - keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions <input type="checkbox"/> Place enough product on skin to cover all surfaces. <input type="checkbox"/> Supervise children under 6 years of age when using this product to avoid swallowing.	
Inactive Ingredients - Water USP.	

HYGENIZE™ HAND SANITIZER

PPE  **ORIGINAL GEL**
Hygiene on a higher level

Helps Prevent the Spread of Germs
Anti-Microbial
Made with Isopropyl Alcohol



32 FL OZ (946.35ML)

Drug Facts

Active Ingredients	Purpose
Isopropyl Alcohol 70% w/v.....	Antimicrobial

Use To help prevent the spread of germs on the skin that could cause disease. For use when soap and water are not available.

Warnings - For external use only.
Flammable. Keep away from heat or flame.
Store below 100°F (41°C)

Do not use ■ On children less than 2 months of age. ■ On broken skin.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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.

Inactive Ingredients Water USP, Methacrylic Acid - Ethyl Acrylate Copolymer.

Made In USA. Distributed by
HYGENIZE Corp., Los Angeles, CA 90068
www.hygenize.com (888) 4943693



60 ml NDC: 80808-002-02

HYGENIZE™ HAND SANITIZER

PPE  **ORIGINAL GEL**
Hygiene on a higher level

With Aloe Vera & Moisturizers
Helps Prevent the Spread of Germs
Anti-Microbial



2 FL OZ (60 ml)

Drug Facts	
Active Ingredients Isopropyl Alcohol 70% v/v.....	Purpose Antimicrobial
Use To help prevent the spread of germs on the skin that could cause disease. For use when soap and water are not available.	
Warnings - For external use only. Flammable. Keep away from heat or flame. Store below 105° F (41° C)	
Do not use ■ On children less than 2 months of age. ■ On broken skin.	
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
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.	
Inactive Ingredients Water USP, Methacrylic Acid, Ethyl Acrylate Copolymer, Glycerin	

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Los Angeles CA.
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40Z Spray / Original



HYGENIZE_1 GALLON_SPRAY-ORIGINAL_LABEL
 CMYK PRINTED ON FOIL SUBSTRATE W MATTE FINISH
 PINK INDICATES TRIM SIZE [4.5" WIDE X 3" HIGH" X .5 CORNER RADIUS]
 TEAL INDICATES BLEED SIZE
 PANTONE 312 C



HYGENIZE ORIGINAL HAND SANITIZER

isopropyl alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80808-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80808-001-94	48 in 1 CARTON	10/04/2020	
1	NDC:80808-001-04	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/04/2020	

HYGENIZE ORIGINAL HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80808-002
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
GLYCERIN (UNII: PDC6A3C0OX)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80808-002-92	48 in 1 CARTON	10/04/2020	
1	NDC:80808-002-02	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		
2	NDC:80808-002-93	12 in 1 CARTON	10/04/2020	
2	NDC:80808-002-32	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
3	NDC:80808-002-98	4 in 1 CARTON	10/04/2020	
3	NDC:80808-002-28	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:80808-002-	48 in 1 CARTON	10/04/2020	

19	48 in 1 CARTON	10/04/2020	
4	NDC:80808-002-09 237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
5	NDC:80808-002-26 32 in 1 CARTON	10/04/2020	
5	NDC:80808-002-16 500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
6	NDC:80808-002-18 48 in 1 CARTON	10/04/2020	
6	NDC:80808-002-08 237 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		
7	NDC:80808-002-14 48 in 1 CARTON	10/04/2020	
7	NDC:80808-002-04 118 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/04/2020	

HYGENIZE ALCOHOL WIPES

alcohol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80808-010
Route of Administration	EXTRACORPOREAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80808-010-81	12 in 1 CARTON	10/04/2020	
1	NDC:80808-010-91	100 in 1 CANISTER		
1	NDC:80808-010-10	5 mL in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:80808-010-86	12 in 1 CARTON	10/04/2020	
2	NDC:80808-010-96	160 in 1 CANISTER		
2	NDC:80808-010-16	5 mL in 1 PATCH; Type 0: Not a Combination Product		
3	NDC:80808-010-98	24 in 1 CARTON	10/04/2020	

3	NDC:80808-010-88	80 in 1 CANISTER		
3	NDC:80808-010-80	5 mL in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	10/04/2020	

Labeler - Hygenize Corp. (089828811)

Establishment

Name	Address	ID/FEI	Business Operations
Topicare Management		079902303	label(80808-002) , repack(80808-002)

Establishment

Name	Address	ID/FEI	Business Operations
Cage		080331158	manufacture(80808-010)

Revised: 10/2020

Hygenize Corp.