

HAND SANITIZER- benzalkonium chloride gel
DGH Pharma, Inc.

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.

Hand Sanitizer Cu - 32015

Active Ingredient(s)

Benzalkonium Chloride 0.10% w/w. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

To eliminate viruses and bacteria on the skin

Warnings

For external use only.

When using this product keep out of eyes. In case of contact, flush eyes with water.

Stop use and ask a doctor if irritation or redness develops

Keep out of reach of children. If swallowed, get medical assistance or contact a Poison Control Center immediately.

Stop use and ask a doctor if irritation or redness develops.

Keep out of reach of children. If swallowed, get medical assistance or contact a Poison Control Center immediately.

Directions

- Rub thoroughly over all surfaces of both hands.
- Rub hands together briskly until dry.

Inactive ingredients

Citrus Sinensis (Orange) Fruit Oil, Copper Chloride, Glycerin, Hydroxyethylcellulose, Magnesium Hydroxide, PEG-8, PEG-90, Phenoxyethanol, Polysorbate 20, Purified Water

Package Label - Principal Display Panel

Ultimate Protection
Our technology first sanitizes your hands and then protects you by disabling harmful pathogens. Your Invisible Glove will penetrate the first layer of the epidermis of the hands. The platelets will remain lodged in the epidermis for more than four hours and remain active. The copper and magnesium platelets utilized are safe for humans. These platelets disable the pathogens by destroying their capsid envelope and disrupting their genetic code.

DIRECTIONS: Put a small amount of Your Invisible Glove on your hands. Spread by rubbing your hands until dry.

Kills COVID-19

XTREME PROTEX™
VIRAL DISRUPTER

MADE IN THE USA

YOUR INVISIBLE GLOVE

4 fl oz (118 mL)

DRUG FACTS

Active ingredients	Purpose
Benzalkonium Chloride 0.10%	Antiseptic
Uses - To eliminate viruses and bacteria on the skin	
Warnings - For external use only.	
When using this product - Keep out of eyes. In case of contact, flush eyes with water.	
Stop use and consult a doctor if irritation or redness develops.	
Keep out of the reach of children. If swallowed, get medical assistance or contact a Poison Control Center immediately.	
Directions - Rub thoroughly over all surfaces of both hands. -Rub hands together briskly until dry.	
Inactive ingredients Citrus Sinensis (Orange) Fruit Oil, Copper Chloride, Glycerin, Hydroxyethylcellulose, Magnesium Hydroxide, PEG-8, PEG-90, Phenoxyethanol, Polysorbate 20, Purified Water	

FDA cGMP Compliant Facility
U.S. Pat. No. 7,892,447 Other Patents Pending "Powered by Aqua"
Manufactured by: DGH PHARMA, INC.
1749 Florida Street • Memphis, Tennessee 38109
XTREMEPROTEX.ME

Package Label for second product

5.57"

IMPACT SOLUTIONS - INVISIBLE GLOVE
Our technology uses nanoplatelets to disable pathogens. When applied to hands, our nanoplatelets will penetrate the first layer of the epidermis of the hands. They will remain lodged in the epidermis for more than four hours and remain active. The copper and magnesium nanoplatelets utilized are safe for humans, but not for the virus. These nanoplatelets disable the pathogens by destroying their capsid envelope and disrupting their genetic code.

DIRECTIONS: Put a small amount of ViraXShield™ Your Invisible Glove on your hands. Spread by rubbing your hands until dry.

NOTE: DO NOT USE ALCOHOL BASED HAND SANITIZER AFTER APPLICATION.

IMPACT SOLUTIONS

For destroying
COVID 19
MRSA
C. difficile
Other Pathogens

WATER BASED
INVISIBLE GLOVE

4 fl oz (118 mL)

DRUG FACTS

This product has not been evaluated by the FDA	
Warnings - For external use only.	
When using this product - Keep out of eyes. In case of contact, flush eyes with water.	
Stop use and consult a doctor if irritation or redness develops.	
Keep out of the reach of children. If swallowed, get medical assistance or contact a Poison Control Center immediately.	
Directions - Rub thoroughly over all surfaces of both hands. -Rub hands together briskly until dry.	
Ingredients Citrus Sinensis (Orange) Fruit Oil, Copper Chloride, Glycerin, Hydroxyethylcellulose, Benzalkonium Chloride, Magnesium Hydroxide, PEG-8, PEG-90, Phenoxyethanol, Polysorbate 20, Purified Water	

IMPACT DIVERSITY SOLUTIONS INC.
15035 N. 75th Street
Scottsdale, AZ 85260

2.35"

HAND SANITIZER
benzalkonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77238-231
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CUPRIC CHLORIDE (UNII: S2QG84156O)	0.201 g in 100 mL
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	0.05 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.65 g in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.4 g in 100 mL
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	1.95 g in 100 mL
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	1.65 g in 100 mL
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	2 g in 100 mL
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	0.65 g in 100 mL
LIMONENE, (+)- (UNII: GFD7C86Q1W)	0.18 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77238-231-14	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
2	NDC:77238-231-24	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/06/2020	
3	NDC:77238-231-11	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/01/2020	
4	NDC:77238-231-31	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2022	
5	NDC:77238-231-41	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/01/2022	
6	NDC:77238-231-44	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2022	
7	NDC:77238-231-48	3785 mL in 1 JUG; Type 0: Not a Combination Product	07/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/01/2020	

Labeler - DGH Pharma, Inc. (128884560)

Registrant - DGH Pharma, Inc. (128884560)

Establishment

Name	Address	ID/FEI	Business Operations
DGH Pharma, Inc.		128884560	manufacture(77238-231)

Revised: 7/2022

DGH Pharma, Inc.