

HAND SANITIZER- benzalkonium chloride spray
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 Spray - 32016

Active Ingredient(s)

Benzalkonium Chloride 0.10% w/w. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Spray on mask and hands to sanitize & protect against bacteria and pathogens.

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

- Spray on hands and on each side of your mask

Inactive ingredients

D-Limonene, Copper Chloride, Glycerin, Magnesium Hydroxide, PEG-8, PEG-90,

Phenoxyethanol, Polysorbate 20, Purified Water, Trisodium Citrate

Package Label - Principal Display Panel

Active ingredients	Purpose
Benzalkonium Chloride 0.10%	Antiseptic
<i>Uses</i> • Spray on mask and hands to sanitize & protect against bacteria and pathogens.	
<i>Warnings</i> - For external use only.	
<i>When using this product</i> • Keep out of eyes. In case of contact, flush eyes with water.	
<i>Stop use and consult a doctor</i> if irritation or redness develops.	
<i>Keep out of the reach of children.</i> If swallowed, get medical assistance or contact a Poison Control Center immediately.	
<i>Directions</i> • Spray on hands and on each side of your mask.	
<i>Inactive ingredients</i> D-Limonene, Copper Chloride, Glycerin, Magnesium Hydroxide, PEG-8, PEG-90, Phenoxyethanol, Polysorbate 20, Purified Water, Trisodium Citrate	

NDC 77238-241-11
U.S. Pat. No. 7,892,447 - Other Patents Pending

Manufactured by: DGH PHARMA, INC.
1749 Florida Street • Memphis, Tennessee 38109
XTREMEPROTEX.ME

8 60003 61635 2

Additional Label

3.0"



IMPACT SOLUTIONS

For destroying
COVID 19
MRSA
C. difficile
Other Pathogens

MASK SPRAY PROTECTOR

1 oz (30 mL)

DRUG FACTS

Active ingredients	Purpose
Benzalkonium Chloride 0.10%	Antiseptic
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<i>Directions</i> - Spray on hands and on each side of your mask.	
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IMPACT DIVERSITY SOLUTIONS INC.
15035 N. 75th Street
Scottsdale, Arizona 85260
<http://www.impactdiversity.com/>

2.25"

HAND SANITIZER

benzalkonium chloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77238-241
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
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	2.2 g in 100 mL
POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ)	0.21 g in 100 mL
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	0.21 g in 100 mL
POLYSORBATE 20 (UNII: 7T1F30V5YH)	0.2 g in 100 mL

PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.4 g in 100 mL
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	0.005 g in 100 mL
CUPRIC CHLORIDE (UNII: S2QG84156O)	0.267 g in 100 mL
LIMONENE, (+)- (UNII: GFD7C86Q1W)	0.1 g in 100 mL
ANHYDROUS TRISODIUM CITRATE (UNII: RS7A450LGA)	0.15 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77238-241-11	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
2	NDC:77238-241-21	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/05/2020	
3	NDC:77238-241-41	30 mL in 1 BOTTLE; 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(77238-241)

Revised: 7/2022

DGH Pharma, Inc.