

HAND PROTECTOR- benzalkonium chloride solution
Cytonix, 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.

Active Ingredient. Benzalkonium Chloride 0.13%

Purpose: Antiseptic. Hand and skin sanitizer.

USES: to reduce bacteria on the skin that could cause disease. Recommended for repeat use.

WARNINGS:

For external use only.

Do not use in the eyes.

When using this product avoid contact with eyes. In case of eye contact flush with water. Stop use and ask doctor if irritation and redness develop.

Keep out of reach of children.

If swallowed, get medical attention or contact a Poison Control Center.

Keep out of reach of children

Avoid contact with eyes. In case of contact flush with plenty of water.

Stop use and ask doctor if irritation or redness develop.

3-(trimethoxysilyl) Propyl Dimethyl Octadecyl Ammonium Chloride, Glycerin, Water

Apply liberally to hands and gently rub until dry. Reapply after 4 hours.

Cytonix, LLC, Beltsville, MD

20705 USA 301-470-6267

www.cytonix.com

Hand Protector Label 79291-654-01 473mL

CYTONIX

HAND PROTECTOR



DRUG FACTS:

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Benzalkonium Chloride 0.13%	Antiseptic

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WARNINGS:

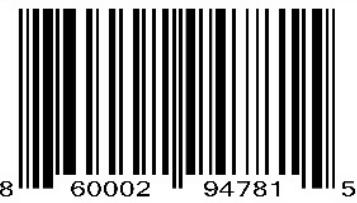
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INACTIVE INGREDIENTS:

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CONTACT: Cytonix LLC, Beltsville, MD 20705, 301-470-6267, www.cytonix.com



HAND PROTECTOR

benzalkonium chloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79291-654
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	98 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 g in 100 mL
OCTADECYLDIMETHYL(3-TRIHYDROXYSILYLPROPYL)AMMONIUM CHLORIDE (UNII: GLJ50K866T)	0.5 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79291-654-01	473 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/18/2020	

Labeler - Cytonix, LLC (831532705)

Registrant - Elaine Lanza (831532705)

Establishment

Name	Address	ID/FEI	Business Operations
Cytonix, LLC		831532705	manufacture(79291-654)

Revised: 9/2020

Cytonix, LLC