

## **DISINFECTANT WIPES- benzalkonium chloride/ isopropyl alcohol cloth**

### **MB Diversity**

*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.*

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### **Disinfectant Wipes**

#### **OTC Monograph Not Final**

This is a disinfectant wipe manufactured according to the FDA Monograph Not Final, regarding Benzalkonium Chloride as a disinfectant, which may be used to battle COVID-19. It has proven effective at destroying coronavirus' envelopes, and many other biocide functions for years. We chose a solution of 0.50% BZK concentration to prevent any topical skin irritation, which has been documented at levels of  $\geq 1\%$  concentrations. We also advise anyone with skin conditions to wear gloves, or any Respiratory problems to use a sufficient Respirator, such as an N-95, because inhalation of BZK has shown complications with individuals who have severe asthma or other Respiratory Problems. We also advise rinsing disinfected surfaces with potable water before placing food on them, to prevent any unwanted ingestions of the BKS.

BKC formulation kills 99.99% of most bacteria, and also influenza as well as molds.

Less than a year ago, the Food and Drug Administration went even further, green-lighting the over-the-counter sale of BZK-manufactured hand hygiene products.

#### **Active Ingredient(s)**

Benzalkonium Chloride 0.5% v/v. Purpose Antiseptic

Alcohol 4% v/v. Purpose: Antiseptic, Necessary to Dilluted BKC

#### **Purpose**

Antiseptic, Multi Surface Disinfectant, and Topical Antiseptic

#### **Use**

Multi-surface and topical Disinfectant wipe to help reduce bacteria that potentially can cause disease.

For use on Non-Porous surfaces to aid in disinfecting.

Recommended for repeated use.

#### **Do not use**

- If you have Respiratory problems.
- On open skin wounds.
- If you suffer from dermatitis, psoriasis, excema.

#### **When using this product**

Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.

Avoid contact with broken skin.

Do not inhale fumes or ingest.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Avoid use on untreated wood or porous surfaces.

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.

### **Warnings**

For external use only. Flammable. Keep away from heat or flame

### **Directions**

- Wipe generously on non porous surfaces to completely cover.
- Wipe until clean, allow to remain visibly wet until surfaces air dry.
- After disinfecting, thoroughly rinse surfaces, with potable water, before coming into direct contact with food.
- Children under 6 years of age should not be using this product.
- Throw away soiled wipes, do not reuse.
- Dispose of wipes in the trash, do not throw into the toilet.
- Avoid eye contact, or swallowing.

### **Other information**

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

### **Inactive ingredients**

Laureth-9 Phosphate, Glycerin, DMDM Hydantoin, Fragrance, RO Water USP

### **Package Label - Principal Display Panel**

480 mL NDC: 78833-010-01

**Drug Facts**

Active Ingredient	Purpose
Benzalkonium Chloride 0.55% w/v Benzalkonium Chloride 0.5% w/v	Antiseptic, Surface Wipe Antiseptic, Property Control Agent

- Uses**
- Disinfectant wipe to help reduce bacteria that potentially can cause disease.
  - For use on Non-Porous surfaces to assist in disinfecting.
  - Recommended for repeated use.

**Warnings**

**For multiple purpose surface disinfectant or external use only -** If you have sensitive skin, use gloves for prolonged exposure to protect hands. People with skin conditions or open wounds should avoid direct contact. Asthmatics or people with respiratory problems should use a respirator to avoid inhaling fumes.

- Flammable** - Keep away from heat or flame.
- Do not use**
- If you have Respiratory problems.
  - On open skin wounds.
  - If you suffer from dermatitis, psoriasis, eczema.

- When using this product**
- Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.
  - Avoid contact with broken skin.
  - Do not inhale fumes or ingest.
  - Keep out of reach of children.
  - If swallowed, get medical help or contact a Poison Control Center right away.
  - Avoid use on untreated wood or porous surfaces.

**Stop use and ask a doctor** if a rash or skin irritation 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**
- Wipe generously on non porous surfaces to completely cover.
  - Wipe and leave, allow to remain visibly wet until surfaces are dry.
  - After disinfecting, thoroughly rinse surfaces, with potable water, before coming into direct contact with food.
  - Children under 6 years of age should not be using this product.
  - Throw away soiled wipes, do not reuse.
  - Dispose of wipes in the trash, do not throw into the toilet.
  - **Avoid eye contact, or swallowing.**

- Other Information**
- Avoid freezing and excessive heat above 100°F
  - Store between 50-90°F
  - May discolor some fabrics.
  - Harsh to untreated wood, some plastics, untreated metal.

**Inactive Ingredients**  
Laurth-3 Propylate, Glycerin, DMDM Hydantoin, Fragrance, RO Water USP

[Package Label - Principal Display Panel's]

17 oz (480 mL)

NDC: 78833-010-01



DISINFECTANT  
WIPES

kills 99.99% of common germs in  
15 seconds

17 oz (480 mL)

# DISINFECTANT WIPES

benzalkonium chloride/ isopropyl alcohol cloth

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78833-010
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	4 mL in 100 mL
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.5 mg in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
DMDM HYDANTOIN (UNII: BYR0546TOW)	0.2 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	3 mL in 100 mL
WATER (UNII: 059QF0KO0R)	87.104 mL in 100 mL
CITRONELLAL (UNII: QB99VZZ7GZ)	0.016 mL in 100 mL
.ALPHA.-PINENE (UNII: JPF3YI7O34)	0.016 mL in 100 mL
LINALOOL, (+)- (UNII: F4VNO44C09)	0.016 mL in 100 mL
LINALYL ACETATE (UNII: 5K47SSQ51G)	0.02 mL in 100 mL
MYRCENE (UNII: 3M39CZS25B)	0.016 mL in 100 mL
LIMONENE DIEPOXIDE (UNII: M6TUW5WEJ9)	0.016 mL in 100 mL
2-METHOXY-1-PROPANOL (UNII: 18B570XOYF)	0.016 mL in 100 mL
CITRAL (UNII: T7EU0O9VPP)	0.016 mL in 100 mL
4-METHYL-1,4-PENTANEDIYL DIMETHACRYLATE (UNII: 3BHT04VYO9)	0.016 mL in 100 mL
DIPROPYLENE GLYCOL (UNII: E107L85C40)	0.016 mL in 100 mL
LAURETH-9 PHOSPHATE (UNII: 0N8G76HI0)	5 mL in 100 mL
.BETA.-PINENE (UNII: 4MS8VHZ1HJ)	0.016 mL in 100 mL
TERPINOLENE (UNII: N9830X5KSL)	0.016 mL in 100 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78833-010-01	480 mL in 1 CYLINDER; Type 0: Not a Combination Product	07/08/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/08/2020	

**Labeler** - MB Diversity (079725725)

**Establishment**

Name	Address	ID/FEI	Business Operations
MB Diversity		079725725	relabel(78833-010)

Revised: 7/2020

MB Diversity