

DISINFECTING WIPES- benzalkonium chloride, didecyl dimethyl ammonium chloride cloth CROWN (YANGZHOU) HEALTH & BEAUTY CO., LTD.

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.

DISINFECTING WIPES

DISINFECTING WIPES

Active Ingredient(s)

Benzalkonium Chloride 0.2%, w/w

DiDecyl dimethyl ammonium chloride 0.2%, w/w

Purpose

Antiseptic

Use

DISINFECTING WIPES 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.

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.

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

Phenoxyethanol
Ethylhexyl glycerin
Propylene Glycol
Glycerin
Purified Water

Package Label - Principal Display Panel

RAIN'S SECRET™
DISINFECTING WIPES

Kills 99.9% of Viruses & Bacteria

Safe on Hand, Finished Wood, Sealed Granite and Stainless Steel

15 WET WIPES

✓ Kills 99.9% of Viruses & Bacteria
✓ Kills Cold and Flu Viruses
✓ Kills 99.999% of Bacteria* in 10 seconds.
✓ Triple Layered for 5x Cleaning Power

Drug Facts

Active Ingredient	Purpose
Benzalkonium chloride-0.2%, Didecyl dimethyl ammonium chloride-0.2%	Antiseptic

Uses: Hand-washing to decrease bacteria on the skin.
Furniture Wood, Sealed Granite, Glass and Stainless Steel

Warnings: Causes moderate eye irritation. Avoid contact with eyes or clothing.
Wash thoroughly with soap and water after handling.

Do not use: near or in the eyes. If contact occurs, rinse eyes with water thoroughly.

Keep safe and use a precaution of irritation, rash, or redness develops.

First aid: IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes.
Remove contact lenses, if present, after the first 5 minutes. Then continue rinsing eye.
Call a poison control center for treatment advice.
*View the product container or label with you when calling a poison control center or doctor, or going for treatment.

Directions: Open the package, cut and apply wipe thoroughly onto hands.
Discard after single use, no rinsing required. Dispose of used wipes in trash receptacle. Do not flush.

Other information: • Should be stored below 110°F(43°C)
• Dispose of wipe in trash after use. Do not flush.

Inactive Ingredients
Phenoxyethanol, Ethylhexylglycerin, Propylene Glycol, Glycerin, Purified Water

To clean and remove allergens: Wipe surface clean with this product. Let air dry.
To disinfect and deodorize hard, nonporous surfaces:
Wipe surface; use enough wipes for treated surface to remain visibly wet for 4 minutes.
Let surface dry. For highly soiled surfaces, clean excess dirt first.
To sanitize hard, nonporous, non-food-contact surfaces:
Wipe surface; use enough wipes for treated surface to remain visibly wet for 30 seconds.
Let surface dry. For highly soiled surfaces, clean excess dirt first.

KEEP OUT OF REACH OF CHILDREN
CAUTION: SEE BACK PANEL FOR ADDITIONAL INFORMATION

Manufactured by
Hill House Medical Device
©2018/01/01

6 920840 572431

Made in China

DISINFECTING WIPES

benzalkonium chloride, didecyl dimethyl ammonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75328-501
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIDECYLDIMONIUM CHLORIDE (UNII: JXN40O9Y9B) (DIDECYLDIMONIUM - UNII:Z7F472XQPA)	DIDECYLDIMONIUM CHLORIDE	0.2 in 100
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.2 in 100

Inactive Ingredients

Ingredient Name	Strength
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75328-501-01	15 in 1 BAG; Type 0: Not a Combination Product	11/13/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/13/2020	

Labeler - CROWN (YANGZHOU) HEALTH & BEAUTY CO., LTD. (542978427)

Establishment

Name	Address	ID/FEI	Business Operations
CROWN (YANGZHOU) HEALTH & BEAUTY CO., LTD.		542978427	manufacture(75328-501)

Revised: 11/2020

CROWN (YANGZHOU) HEALTH & BEAUTY CO., LTD.