

HAND SANITIZING WIPES- benzalkonium chloride cloth
BELLA BRANDS 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 Sanitizing Wipes

Drug Facts:

Active Ingredient

Benzalkonium Chloride, 0.13%

Purpose

Antimicrobial Agent

Use

for cleaning hands and decreasing bacteria on the skin.

Warnings

- For external use only.
- Do not use if you are allergic to any of the ingredients.
- When using this product, do not get into eyes. If contact occurs, rinse thoroughly with water.
- Stop use and consult a doctor if irritation or rash develops and continues for more than 72 hours.
- Keep out of reach of children. If swallowed, get medical help or visit a Poison Control Center right away.

Inactive Ingredients

C12-14 Alkyl Dimethyl, Ethylbenzyl Ammonium Chloride, Alkyl Polyglucoside, Disodium EDTA, Propylene Glycol, Aloe Vera Leaf Juice (Organic), Aqua.

Directions For Use

- Press dispensing pump to release product into hands, add water and rub thoroughly around both sides of hands and between fingers. Rinse off and towel dry.
- For adults and children 2 years and over.
- For children under 2 years of age, consult a doctor before use.

Directions

- Tear open dispensing cap and remove entire lid from canister.
- Locate wipe at center of the roll, twist corner to a point and thread through small opening in lid.
- Replace lid and pull wipe up at an angle. Remaining wipes feed automatically.
- Snap lid cap shut to retain moisture when finished.

Adults and children 2 years and over
 Apply to hands, Allow skin to dry without wiping
 Children under 2 years, ask a doctor before use

Manufactured for Bella Brands Inc.
 Aliso Viejo, California
 By Ningbo Riway Daily Commodity Co Ltd.
 Ningbo City, Zhejiang Province

PRINCIPAL DISPLAY PANEL - 500 Wipe Canister Label

PURIGEN™

Hand Sanitizing Wipes

- Kills 99.9% of Germs
- Clean Hands On-The-Go
- Safe for Sensitive Skin
- Made with Organic Aloe Vera

500
 Wipes
 17.5 x 17 cm



HAND SANITIZING WIPES
 benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80994-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Edetate Disodium Anhydrous (UNII: 8NLQ36F6MM)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80994-005-01	160 in 1 CANISTER	05/01/2020	
1		0.0044 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
2	NDC:80994-005-02	500 in 1 CANISTER	05/01/2020	
2		0.0044 mL in 1 APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/01/2020	

Labeler - BELLA BRANDS INC (034908755)**Establishment**

Name	Address	ID/FEI	Business Operations
BELLA BRANDS INC		034908755	MANUFACTURE(80994-005)

Establishment

Name	Address	ID/FEI	Business Operations
Ningbo Riway Nonwovens Tech Co., LTD.		540997562	MANUFACTURE(80994-005)

