MONK HAND SANITIZING WIPES- benzethonium chloride cloth National Towelette Company

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.

Image of Label

Principal Display Panel

MM1



Active Ingredients:

Benzethonium Chloride (0.3%)

Purpose:

Antibacterial

Use decreases bacteria on skin

Warnings For external use only

Do not use

- over large areas
- 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 ask 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 contact Poison Control Center right away.

Directions: Adults and children 2 years and over: apply on hands and face to clean and refresh. Allow skin to dry without wiping. Children under 2 years: as a doctor before use. For Children under 6 use only under supervision.

Inactive Ingredients: Water, SD Alcohol 40-B, Sodium Benzoate, Diazolidinyl Urea, Glycerin, Propylene Glycol, Potassium Sorbate, Disodium EDTA, Tocopheryl Acetate, Aloe

Store under 110 F

Questions and Comments: For products or technical information, contact National Towelette Monday to Friday 8 AM to 4 PM EST at 1-800-738-9068, or visit our website at www.towelettes.com

MONK HAND SANITIZING WIPES

benzethonium chloride cloth

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50320-111	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Benzethonium Chloride (UNII: PH41D05744) (Benzethonium - UNII:1VU15B70BP)	Benzethonium Chloride	30 mL in 1000 mL		

Inactive Ingredients				
Ingredient Name	Strength			
Water (UNII: 059QF0KO0R)	879 mL in 1000 mL			
Ethanol (UNII: 3K9958V90M)	111.60 mL in 1000 mL			
Sodium Benzoate (UNII: OJ245FE5EU)	1.30 mL in 1000 mL			
Diazolidinylurea (UNII: H5RIZ3MPW4)	1.30 mL in 1000 mL			
Glycerin (UNII: PDC6A3C0OX)	1.00 mL in 1000 mL			
Propylene Glycol (UNII: 6DC9Q167V3)	1.00 mL in 1000 mL			
Potassium Sorbate (UNII: 1VPU26JZZ4)	.75 mL in 1000 mL			
Edetate Disodium (UNII: 7FLD91C86K)	.45 mL in 1000 mL			
Alpha-Tocopherol Acetate (UNII: 9E8X80D2L0)	0.10 mL in 1000 mL			
Aloe (UNII: V5VD430 YW9)	0.09 mL in 1000 mL			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50320-111-58	500 mL in 1 CANISTER		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333	0 1/0 6/20 10		

Labeler - National Towelette Company (782795041)

Registrant - National Towelette Company (782795041)

Establishment				
Name	Address	ID/FEI	Business Operations	
National Towelette Company		782795041	repack	

Revised: 1/2010 National Towelette Company