HAND SANITIZING WIPES- benzalkonium chloride cloth Jurong Dongfa General Merchandise 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.

75127-001 HAND SANITIZING WIPES

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antiseptic

USE

- •For hand sanitizing to decrease bacteria on the skin.
- •Apply topically to the skin to help prevent cross contamination.
- Recommended for repeated use.
- Dries in seconds.

Warning

For external use only Do not use in the eyes

•Keep out of reach of children unless under adult supervision.

Directions

·Wet hands thoroughly with product and allow to dry without wiping.

Other information

- ·Store below 104°F∏40°C∏
- ·May discolor certain Fabrics.

Inactive ingredients

Polyaminopropyl biguanide Diazolidinyl urea Propylene Glycol Glycerin Benzalkonium chloride Cocamidopropyl Betaine PEG40 Hydrogenated castor oil Aloe Barbadensis Leaf Extract Aqua

Drug Facts

ACTIVE INGREDIENTS Purpose Benzalkonium chloride 0.13%......Antiseptic

Uses

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Polyaminopropyl biguanide, Diazolidinyl urea, Propylene Glycol, Glycerin, Benzalkonium chloride, Cocamidopropyl Betaine, PEG40 Hydrogenated castor oil, Aloe Barbadensis Leaf Extract, Aqua

HAND SANITIZING WIPES

benzalkonium chloride cloth

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:75127-001

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

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
POLYAMINOPROPYL BIGUANIDE (UNII: DT9D8Z79ET)				
GLYCERIN (UNII: PDC6A3C0OX)				
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75127-001- 01	200 in 1 CARTON	04/21/2020	
1		10 in 1 BAG		
1		4 g in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:75127-001- 02	72 in 1 CARTON	04/21/2020	
2		25 in 1 BAG		
2		4.04 g in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:75127-001- 03	24 in 1 CARTON	04/21/2020	
3		80 in 1 BAG		
3		4.05 g in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:75127-001- 04	6 in 1 CARTON	04/21/2020	
4		800 in 1 BAG		
4		3.6 g in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:75127-001- 05	4 in 1 CARTON	04/21/2020	
5		1200 in 1 BAG		
5		3.6 g in 1 POUCH; Type 0: Not a Combination Product		
6	NDC:75127-001- 06	8 in 1 CARTON	04/21/2020	
6		200 in 1 BAG		
_		4.05 g in 1 POUCH; Type 0: Not a Combination		

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7	NDC:75127-001- 07	200 in 1 CARTON	04/21/2020	
7		15 in 1 BAG		
7		4 g in 1 POUCH; Type 0: Not a Combination Product		
8	NDC:75127-001- 08	40 in 1 CARTON	04/21/2020	
8		50 in 1 BAG		
8		4.04 g in 1 POUCH; 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	04/21/2020		

Labeler - Jurong Dongfa General Merchandise Co Ltd (528077612)

Establishment					
Name	Address	ID/FEI	Business Operations		
Jurong Dongfa General Merchandise Co Ltd		528077612	manufacture(75127-001)		

Revised: 2/2022 Jurong Dongfa General Merchandise Co Ltd