

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.

75127-007 HAND SANITIZING WIPES 0.13% Benzalkonium chloride

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

Remove lid.
Pull wipe from center of roll and thread through opening in lid. Do not push finger through opening.
Replace lid, pull wipe up, and then out at 45° angle. The next wipe dispenses automatically.
·Close lid to retain moisture.

Inactive ingredients

Water, Propylene Glycol, Disodium EDTA, Chloro-methyl-isothiazolinone and Methyl-isothiazolinone, Potassium Sorbate, Quaternium-15, Aloe Barbadensis Leaf Juice, Disodium Cocoamphodiacetate, Vitamin E Acetate Polysorbate-20, Citric Acid, Fragrance.



HAND SANITIZING WIPES

benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75127-007
Route of Administration	TOPICAL		

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
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
QUATERNIUM-15 (UNII: E40U03LEM0)	
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE SODIUM (UNII: MP1J8420LU)	
DISODIUM COCOAMPHODIACETATE (UNII: 18L9G3U51M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75127-007-01	200 in 1 CARTON	10/20/2020	
1		10 in 1 BAG		
1		4 g in 1 POUCH; Type 0: Not a Combination Product		

2	NDC:75127-007-02	6 in 1 CARTON	10/20/2020	
2		240 in 1 PAIL		
2		4.04 g in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:75127-007-03	24 in 1 CARTON	10/20/2020	
3		80 in 1 BAG		
3		4.05 g in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:75127-007-04	4 in 1 CARTON	10/20/2020	
4		800 in 1 BAG		
4		4.05 g in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:75127-007-05	4 in 1 CARTON	10/20/2020	
5		1200 in 1 BAG		
5		4.05 g in 1 POUCH; Type 0: Not a Combination Product		
6	NDC:75127-007-06	8 in 1 CARTON	10/20/2020	
6		200 in 1 PAIL		
6		4.05 g in 1 POUCH; Type 0: Not a Combination Product		
7	NDC:75127-007-07	200 in 1 CARTON	10/20/2020	
7		15 in 1 BAG		
7		4 g in 1 POUCH; Type 0: Not a Combination Product		
8	NDC:75127-007-08	40 in 1 CARTON	10/20/2020	
8		50 in 1 BAG		
8		4.04 g in 1 POUCH; Type 0: Not a Combination Product		
9	NDC:75127-007-09	12 in 1 CARTON	10/20/2020	
9		240 in 1 PAIL		
9		4.04 g in 1 POUCH; Type 0: Not a Combination Product		
10	NDC:75127-007-10	4 in 1 CARTON	10/20/2020	
10		1500 in 1 BAG		
10		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	10/20/2020	

Establishment

Name	Address	ID/FEI	Business Operations
Jurong Dongfa General Merchandise Co Ltd		528077612	manufacture(75127-007)

Revised: 2/2022

Jurong Dongfa General Merchandise Co Ltd