ANTI-BACTERIAL WET WIPES- benzalkonium chloride cloth Dalian Daxin Nonwoven Technology 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.

78028-004 ANTI-BACTERIAL WET WIPES 0.13% BENZALKONIUM CHLORIDE

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antiseptic/Hand & Skin Sanitizer

USE

Sanitizing Hand Wipes to help decrease bacteria on the skin. Recommended for single use.

Do not freeze. For external use only, Store at room temperature. Do not use in ears, eyes or mouth. Avoid contact with the eyes. In case of contact, flush eyes with water. Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours,

- •Keep out of reach of children.
- •Children should be supervised when using this product. If swallowed, get medical help or contact Poison Control Centre immediately.

Directions

Wipe liberally over the hands & body, rub into skin until dry, Recommended for single use.

Inactive ingredients

Water (Aqua), Glycerol, Propanediol, Aloe Vera Extract, Amino acid moisturizer, Hexadecylpyridinium Chloride, Chlorphenesin, Vitamin E, Dodecyl polyglucoside, Citric acid, Sodium citrate.



ANTI-BACTERIAL WET WIPES

benzalkonium chloride cloth

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:78028-004

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Active ingredient/Active Molety				
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
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
.ALPHATOCOPHEROL (UNII: H4N855PNZ1)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLY(LAURYLGLUCOSIDE)-7 (UNII: VB00RDE21R)	
PROPANEDIOL (UNII: 5965N8W85T)	
BETAINE (UNII: 3SCV180C9W)	
CETYLPYRIDINIUM CHLORIDE ANHYDROUS (UNII: 6BR7T22E2S)	
CHLORPHENESIN (UNII: 1670DAL4SZ)	
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78028- 004-01	50 in 1 PAIL	07/20/2020	

1		6.5 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
2	NDC:78028- 004-02	70 in 1 PAIL	07/20/2020	
2		6.5 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
3	NDC:78028- 004-03	80 in 1 PAIL	07/20/2020	
3		6.5 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
4	NDC:78028- 004-04	100 in 1 PAIL	07/20/2020	
4		6.5 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
5	NDC:78028- 004-05	30 in 1 BAG	07/20/2020	
5		6.5 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
6	NDC:78028- 004-06	40 in 1 BAG	07/20/2020	
6		6.5 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
7	NDC:78028- 004-07	50 in 1 BAG	07/20/2020	
7		6.5 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
8	NDC:78028- 004-08	60 in 1 BAG	07/20/2020	
8		6.5 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
9	NDC:78028- 004-09	80 in 1 BAG	07/20/2020	
9		6.5 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
10	NDC:78028- 004-10	150 in 1 PAIL	07/20/2020	
10		6.5 g in 1 NOT APPLICABLE; 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	07/20/2020	

Labeler - Dalian Daxin Nonwoven Technology Co., Ltd. (415363991)

Establishment					
Name	Address	ID/FEI	Business Operations		
Dalian Daxin Nonwoven Technology Co., Ltd.		415363991	manufacture(78028-004)		