

DISINFECTING WIPES- didecyldimonium chloride, benzalkonium chloride cloth
Zhejiang Aijian Sanitary Products 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.

77850-001 Disinfecting Wipes

Benzalkonium Chloride 0.13 %

Didecyldimonium Chloride 0.1 5%

antiseptic

USE

For hand sanitizing to decrease bacteria on the skin
This wipes do not replace wipes used for medical procedures
This wipes are meant for general cleaning

Warning

For external use only
Do not use in or contact the eyes
keep this out of reach of children. Store below 95 F(35 C)
If swallowed, get medical help or contact a Poison Control Center immediately
Keep in a dry place away from fire
Discontinue use if irritation and redness develop. If the condition persists for more than 72 hours, consult a physician.
Please close the lid after dispensing to maintain purity.
Keep this out of reach of children

Directions

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

Inactive ingredients

Purified Water, Glycerin, Aloe Barbadensis extract, Phenoxyethanol, Ethylhexylglycerin, Propylene Glycol.

Drug Facts

ACTIVE INGREDIENTS	Purpose
Benzalkonium Chloride 0.13%	Antiseptic
Didecyldimonium Chloride 0.15%	Antiseptic

Uses For hand sanitizing to decrease bacteria on the skin
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DISINFECTING WIPES

didecyldimonium chloride,benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77850-001
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIDECYLDIMONIUM CHLORIDE (UNII: JXN40O9Y9B) (DIDECYLDIMONIUM - UNII:Z7F472XQPA)	DIDECYLDIMONIUM CHLORIDE	0.15 g in 100 g
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77850-001-01	10 in 1 BAG	05/20/2020	
1		4.4 g in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:77850-001-02	30 in 1 BAG	05/20/2020	
2		4.4 g in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:77850-001-03	50 in 1 BAG	05/20/2020	
3		4.4 g in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:77850-001-04	160 in 1 PAIL	05/20/2020	
4		4.4 g in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:77850-001-05	80 in 1 BAG	05/20/2020	
5		4.4 g in 1 POUCH; Type 0: Not a Combination Product		
6	NDC:77850-001-06	100 in 1 BAG	05/20/2020	
6		4.4 g in 1 POUCH; Type 0: Not a Combination Product		
7	NDC:77850-001-07	100 in 1 PAIL	05/20/2020	
7		4.4 g in 1 POUCH; Type 0: Not a Combination Product		
8	NDC:77850-001-08	120 in 1 PAIL	05/20/2020	
8		4.4 g in 1 POUCH; Type 0: Not a Combination Product		
9	NDC:77850-001-09	150 in 1 PAIL	05/20/2020	
9		4.4 g in 1 POUCH; Type 0: Not a Combination Product		
10	NDC:77850-001-10	900 in 1 PAIL	05/20/2020	
10		4.4 g in 1 POUCH; Type 0: Not a Combination Product		
11	NDC:77850-001-11	20 in 1 BAG	05/20/2020	
11		4.4 g in 1 POUCH; Type 0: Not a Combination Product		
12	NDC:77850-001-12	60 in 1 BAG	05/20/2020	
12		4.4 g in 1 POUCH; Type 0: Not a Combination Product		
13	NDC:77850-001-13	70 in 1 BAG	05/20/2020	
13		4.4 g in 1 POUCH; Type 0: Not a Combination Product		
14	NDC:77850-001-14	800 in 1 BAG	05/20/2020	

14		4.4 g in 1 POUCH; Type 0: Not a Combination Product		
15	NDC:77850-001-15	1000 in 1 BAG	05/20/2020	
15		4.4 g in 1 POUCH; Type 0: Not a Combination Product		
16	NDC:77850-001-16	60 in 1 PAIL	05/20/2020	
16		4.4 g in 1 POUCH; Type 0: Not a Combination Product		
17	NDC:77850-001-17	70 in 1 PAIL	05/20/2020	
17		4.4 g in 1 POUCH; Type 0: Not a Combination Product		
18	NDC:77850-001-18	80 in 1 PAIL	05/20/2020	
18		4.4 g in 1 POUCH; Type 0: Not a Combination Product		
19	NDC:77850-001-19	800 in 1 PAIL	05/20/2020	
19		4.4 g in 1 POUCH; Type 0: Not a Combination Product		
20	NDC:77850-001-20	1000 in 1 PAIL	05/20/2020	
20		4.4 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	05/20/2020	

Labeler - Zhejiang Aijian Sanitary Products Technology Co., Ltd. (554495636)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Aijian Sanitary Products Technology Co., Ltd.		554495636	manufacture(77850-001)

Revised: 8/2020

Zhejiang Aijian Sanitary Products Technology Co., Ltd.