

**ANTIBACTERIAL WET WIPES- benzalkonium chloride swab**  
**Hangzhou Haorun 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.*

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**Antibacterial Wet Wipes**

**Active Ingredient**

Benzalkonium chloride 0.13%

**Purpose**

Antibacterial

**Use**

for hand washing to decrease bacteria on skin

**WARNINGS**

For External use only.

Do not use 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.

Discontinue use if irritation or redness develops if condition persists for more than 72 hours consults a physician.

**keep out of reach of children**

keep out of reach of children unless under adult supervision .if seallowed ,get medical help or contact a Poison Control Center immediately.

**Directions**

Thoroughly wipe hands or face with wipe,Discard in trash receptacle;do not flush.Be sure to reseal label complete to retain moisture

**Inactive ingredients**

WATER PROPYLENE GLYCOL OCTHILINONE .ALPHA.-TOCOPHEROL

<b>Drug Facts</b>		<b>Antibacterial Wet Wipes</b>		<b>Drug Fact (Continued)</b>	
<b>Active Ingredient</b>		<b>Purpose</b>		<b>Directions For Use</b>	
Benzalkonium chloride 0.13%.....		Antiseptic		Thoroughly wipe hands or face with wipe. Discard in trash receptacle; do not flush. Be sure to reseal label complete to retain moisture.	
<b>Uses</b>		For hand washing to decrease bacteria on skin		<b>Inactive Ingredients</b>	
<b>Warnings</b>		<ul style="list-style-type: none"> <li>■ For external use only</li> <li>■ Do not use if you are allergic to any of the ingredients</li> <li>■ When using this products do not get into eyes, if contact occurs, rinse thoroughly with water.</li> <li>■ Discontinus use if irritation or redness develops if condition persists for more than 72 hours consult a physician.</li> <li>■ Keep out of reach of children unless under adult supervision. If swallowed, get medical help or contact a Poison Control center immediately.</li> </ul>		Water, prepylene Glycol, Disodium EDTA, Chloromethylisothiazolinone & Methlisoithiazolinone. Potassium Sorbate, Quaternium-15, Aloe Barbadensis Leaf Juice. Dissodium cocoamphodjacetate, Tocophery Acetate, polysorbate-20, Citric acid, Fragrance.	
		Made In China		Manufactured by : Hangzhou Haorun Technology Co., Ltd	

<b>ANTIBACTERIAL WET WIPES</b>				
benzalkonium chloride swab				
<b>Product Information</b>				
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:578 17-100	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	<b>Benzalkonium Chloride</b> (UNII: F5UM2KM3W7) (Benzalkonium - UNII:7N6JUD5X6 Y)	Benzalkonium Chloride	0.13 g in 100 g	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>	<b>Strength</b>		
	<b>WATER</b> (UNII: 059QF0KO0R)			
	<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)			
	<b>OCTHILINONE</b> (UNII: 4LFS24GD0V)			
	<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)			
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:578 17-100-01	1 in 1 BOTTLE		
1		10 g in 1 POUCH		
2	NDC:578 17-100-02	2 in 1 BOTTLE		
2		8 g in 1 POUCH		
3	NDC:578 17-100-03	3 in 1 BOTTLE		
3		6 g in 1 POUCH		
4	NDC:578 17-100-04	4 in 1 BOTTLE		
4		5 g in 1 POUCH		
5	NDC:578 17-100-05	5 in 1 BOTTLE		
5		5 g in 1 POUCH		

6	NDC:578 17-100-06	6 in 1 BOTTLE		
6		5 g in 1 POUCH		
7	NDC:578 17-100-07	7 in 1 BOTTLE		
7		5 g in 1 POUCH		
8	NDC:578 17-100-08	8 in 1 BOTTLE		
8		5 g in 1 POUCH		
9	NDC:578 17-100-09	9 in 1 BOTTLE		
9		5 g in 1 POUCH		
10	NDC:578 17-100-10	10 in 1 BOTTLE		
10		3.5 g in 1 POUCH		
11	NDC:578 17-100-11	12 in 1 BOTTLE		
11		3.5 g in 1 POUCH		
12	NDC:578 17-100-12	15 in 1 BOTTLE		
12		3 g in 1 POUCH		
13	NDC:578 17-100-13	18 in 1 BOTTLE		
13		3 g in 1 POUCH		
14	NDC:578 17-100-14	20 in 1 BOTTLE		
14		3 g in 1 POUCH		
15	NDC:578 17-100-15	25 in 1 BOTTLE		
15		3 g in 1 POUCH		
16	NDC:578 17-100-16	30 in 1 BOTTLE		
16		2.5 g in 1 POUCH		
17	NDC:578 17-100-17	35 in 1 BOTTLE		
17		2.5 g in 1 POUCH		
18	NDC:578 17-100-18	40 in 1 BOTTLE		
18		2.5 g in 1 POUCH		
19	NDC:578 17-100-19	45 in 1 BOTTLE		
19		2.5 g in 1 POUCH		
20	NDC:578 17-100-20	50 in 1 BOTTLE		
20		2.5 g in 1 POUCH		
21	NDC:578 17-100-21	60 in 1 BOTTLE		
21		2.5 g in 1 POUCH		
22	NDC:578 17-100-22	72 in 1 BOTTLE		
22		2.5 g in 1 POUCH		
23	NDC:578 17-100-23	80 in 1 BOTTLE		
23		2.5 g in 1 POUCH		
24	NDC:578 17-100-24	90 in 1 BOTTLE		
24		2.5 g in 1 POUCH		
25	NDC:578 17-100-25	100 in 1 BOTTLE		
25		2.5 g in 1 POUCH		
26	NDC:578 17-100-26	110 in 1 BOTTLE		
26		2.5 g in 1 POUCH		
27	NDC:578 17-100-27	120 in 1 BOTTLE		
27		2.5 g in 1 POUCH		
28	NDC:578 17-100-28	150 in 1 BOTTLE		
28		2.5 g in 1 POUCH		
29	NDC:578 17-100-29	180 in 1 BOTTLE		
29		2.5 g in 1 POUCH		
30	NDC:578 17-100-30	200 in 1 BOTTLE		
30		2.5 g in 1 POUCH		

31	NDC:578 17-100-31	250 in 1 BOTTLE		
31		2.5 g in 1 POUCH		
32	NDC:578 17-100-32	300 in 1 BOTTLE		
32		2.5 g in 1 POUCH		
33	NDC:578 17-100-33	400 in 1 BOTTLE		
33		2.5 g in 1 POUCH		
34	NDC:578 17-100-34	1 in 1 PACKAGE		
34		3 g in 1 POUCH		
35	NDC:578 17-100-35	2 in 1 PACKAGE		
35		3 g in 1 POUCH		
36	NDC:578 17-100-36	3 in 1 PACKAGE		
36		3 g in 1 POUCH		
37	NDC:578 17-100-37	4 in 1 PACKAGE		
37		3 g in 1 POUCH		
38	NDC:578 17-100-38	5 in 1 PACKAGE		
38		3 g in 1 POUCH		
39	NDC:578 17-100-39	6 in 1 PACKAGE		
39		3.5 g in 1 POUCH		
40	NDC:578 17-100-40	7 in 1 PACKAGE		
40		3.5 g in 1 POUCH		
41	NDC:578 17-100-41	8 in 1 PACKAGE		
41		3.5 g in 1 POUCH		
42	NDC:578 17-100-42	9 in 1 PACKAGE		
42		3.5 g in 1 POUCH		
43	NDC:578 17-100-43	10 in 1 PACKAGE		
43		4 g in 1 POUCH		
44	NDC:578 17-100-44	12 in 1 PACKAGE		
44		4 g in 1 POUCH		
45	NDC:578 17-100-45	15 in 1 PACKAGE		
45		4 g in 1 POUCH		
46	NDC:578 17-100-46	18 in 1 PACKAGE		
46		4 g in 1 POUCH		
47	NDC:578 17-100-47	20 in 1 PACKAGE		
47		4 g in 1 POUCH		
48	NDC:578 17-100-48	25 in 1 PACKAGE		
48		4 g in 1 POUCH		
49	NDC:578 17-100-49	30 in 1 PACKAGE		
49		4 g in 1 POUCH		
50	NDC:578 17-100-50	35 in 1 PACKAGE		
50		4 g in 1 POUCH		
51	NDC:578 17-100-51	40 in 1 PACKAGE		
51		4 g in 1 POUCH		
52	NDC:578 17-100-52	45 in 1 PACKAGE		
52		4 g in 1 POUCH		
53	NDC:578 17-100-53	50 in 1 PACKAGE		
53		4 g in 1 POUCH		
54	NDC:578 17-100-54	60 in 1 PACKAGE		
54		4 g in 1 POUCH		
55	NDC:578 17-100-55	72 in 1 PACKAGE		
55		4 g in 1 POUCH		

56	NDC:578 17-100-56	80 in 1 PACKAGE		
56		4 g in 1 POUCH		
57	NDC:578 17-100-57	90 in 1 PACKAGE		
57		4 g in 1 POUCH		
58	NDC:578 17-100-58	100 in 1 PACKAGE		
58		4 g in 1 POUCH		
59	NDC:578 17-100-59	110 in 1 PACKAGE		
59		4 g in 1 POUCH		
60	NDC:578 17-100-60	120 in 1 PACKAGE		
60		4 g in 1 POUCH		
61	NDC:578 17-100-61	150 in 1 PACKAGE		
61		4 g in 1 POUCH		
62	NDC:578 17-100-62	180 in 1 PACKAGE		
62		4 g in 1 POUCH		
63	NDC:578 17-100-63	200 in 1 PACKAGE		
63		4 g in 1 POUCH		
64	NDC:578 17-100-64	250 in 1 PACKAGE		
64		4 g in 1 POUCH		
65	NDC:578 17-100-65	350 in 1 PACKAGE		
65		4 g in 1 POUCH		
66	NDC:578 17-100-66	400 in 1 PACKAGE		
66		4 g in 1 POUCH		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/29/2013	

**Labeler** - Hangzhou Haorun Technology CO.,LTD. (421308583)

## Establishment

Name	Address	ID/FEI	Business Operations
Hangzhou Haorun Technology CO.,LTD.		421308583	manufacture(578 17-100)

Revised: 3/2013

Hangzhou Haorun Technology CO.,LTD.