

**FRESHANDS INSTANT FOAMING ANTISEPTIC HAND AND BODY WASH-
chloroxylenol soap
Spa Concepts, Inc.**

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.

FresHands Instant Foaming Antiseptic Hand & Body Wash 6876 Drug facts and Label

Drug Facts Box OTC-Active Ingredient Section

Chloroxylenol 0.3%

Drug Facts Box OTC-Purpose Section

Antiseptic

Drug Facts Box OTC-Indications & Usage Section

for hand-washing to decrease bacteria on the skin

Drug Facts Box OTC-Warnings Section

For external use only

Drug Facts Box OTC-When Using Section

do not get into eyes

if contact occurs, rinse eyes thoroughly with water

Drug Facts Box OTC-Stop Use Section

irritation and redness develop

Drug Facts Box OTC-Keep Out of Reach of Children Section

if swallowed, get medical help or contact a Poison Control Center right away

Drug Facts Box OTC-Dosage & Administration Section

- wet hands and forearms
- apply 5 milliliters (teaspoonful) or palmful to hands and forearms
- scrub thoroughly for 1 minute and rinse

Drug Facts Box OTC-Inactive Ingredient Section

water, decyl glucoside, sodium laureth sulfate, cocamide MIPA, propylene glycol, DMDM hydantoin, fragrance, methylchloroisothiazolinone, methylisothiazolinone, aloe barbadensis, acid red 1

FresHands Instant Foaming Antiseptic Hand & Body Wash 6876



Net Contents: 18 oz (532ml)

SP
FresHands An effective antibacterial hand soap for use in hotels, athletic facilities, correctional facilities, business/office buildings, dressing rooms, factories, institutional facilities, locker rooms, nurseries, shower and bath areas, public facilities, public rest rooms, schools, day care centers, and camp grounds.
 This formulation effectively reduces the bacterial flora of the skin. When tested via the Time Kill Test, it demonstrates 99% or greater kill against *Staphylococcus aureus*, *E. Coli*, and *Pseudomonas aeruginosa*. Formulated with skin conditioners for extra mildness.



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Distributed by: Sanitation Products of America
 3191 West Tharpe Street, Tallahassee FL 32303
 www.sanitationproductsofamerica.com



Net Contents: 18 oz (532ml)

Drug Facts	
Active Ingredient	Purpose
Chloroxylenol 0.3%	Antiseptic
Use for hand-washing to decrease bacteria on the skin	
Warnings	
For external use only	
When using this product	
<ul style="list-style-type: none"> ■ do not get into eyes ■ if contact occurs, rinse eyes thoroughly with water 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> ■ Irritation and redness develop 	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away	
Directions	
<ul style="list-style-type: none"> ■ Wet hands and forearms ■ apply 5 milliliters (teaspoonful) or palmful to hands and forearms ■ scrub thoroughly for 1 minute and rinse 	
Inactive Ingredients water, decyl glucoside, sodium laureth sulfate, cocamide MIPA, propylene glycol, DMDM hydantoin, fragrance, methylchloroisothiazolinone, methylisothiazolinone, aloe barbadensis, acid red 1	

FresHands Instant Foaming Hand & Body Wash

FRESHHANDS INSTANT FOAMING ANTISEPTIC HAND AND BODY WASH

chloroxylenol soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76287-876
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
ACID RED 1 (UNII: 3365R6427R)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76287-876-06	1 in 1 BOX	01/04/2017	
1		800 mL in 1 BAG; Type 0: Not a Combination Product		

2	NDC:76287-876-17	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/04/2017	
3	NDC:76287-876-24	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/04/2017	
4	NDC:76287-876-01	1200 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	01/04/2017	
5	NDC:76287-876-03	350 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	01/04/2017	
6	NDC:76287-876-05	540 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/04/2017	
7	NDC:76287-876-07	700 mL in 1 BAG; Type 0: Not a Combination Product	01/04/2017	
8	NDC:76287-876-09	2000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	01/04/2017	
9	NDC:76287-876-10	1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	01/04/2017	
10	NDC:76287-876-11	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/04/2017	
11	NDC:76287-876-12	1000 mL in 1 BAG; Type 0: Not a Combination Product	01/04/2017	
12	NDC:76287-876-13	800 mL in 1 BAG; Type 0: Not a Combination Product	01/04/2017	
13	NDC:76287-876-14	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/04/2017	
14	NDC:76287-876-15	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/04/2017	
15	NDC:76287-876-28	149 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/04/2017	
16	NDC:76287-876-27	800 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	01/04/2017	
17	NDC:76287-876-55	208200 mL in 1 DRUM; Type 0: Not a Combination Product	01/04/2017	
18	NDC:76287-876-08	1 in 1 BOX	01/04/2017	
18		1000 mL in 1 BAG; Type 0: Not a Combination Product		
19	NDC:76287-876-16	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/04/2017	
20	NDC:76287-876-18	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/04/2017	
21	NDC:76287-876-19	18900 mL in 1 CONTAINER; Type 0: Not a Combination Product	01/04/2017	
22	NDC:76287-876-20	75600 mL in 1 DRUM; Type 0: Not a Combination Product	01/04/2017	
23	NDC:76287-876-35	132500 mL in 1 DRUM; Type 0: Not a Combination Product	01/04/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	01/04/2017	

Labeler - Spa Concepts, Inc. (609438671)

Registrant - ABC Compounding Co., Inc. (003284353)

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(76287-876)

Revised: 12/2018

Spa Concepts, Inc.