

**FRESHANDS - triclosan 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.*

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**FresHands 6576 Drug Facts and Label**

**Drug Facts Box OTC-Active Ingredient Section**

Triclosan 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, sodium laureth sulfate, sodium lauryl sulfate, cocamidopropyl betaine, alcohol denat., propylene glycol, tetrasodium EDTA, PEG-75 lanolin, boric acid, lauramine oxide, chloroxylenol, methylparaben, propylparaben, fragrance, aloe barbadensis, acid red 1, reactive green 12

# FresHands 6544 18oz

657618P6283.jpg FresHands 18oz



**High Foaming**  
**Antimicrobial Hand and Body Wash**  
**Health-Care Personnel Handwash**  
 Net Contents: 18 oz (532ml)

**SP**  
**FresHands** is a high foaming Antimicrobial and Antibacterial soap with Triclosan, effective against E. Coli, Staphylococcus Aureus and Serratia Marcescens. For use in food service establishments, schools, offices, hospitals, nursing homes, etc. Leaves hands smelling fresh and clean. Enhanced with emollients and skin conditioners to ensure mildness, even with frequent hand washings.



8 22788 43011 0  
 Distributed by: **Sanitation Products of America**  
 Spa Concepts, Inc.  
 1630A Old Bainbridge Road  
 Tallahassee, Florida 32303  
 www.sanitationproductsofamerica.com



**High Foaming**  
**Antimicrobial Hand and Body Wash**  
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Drug Facts	
Active Ingredient	Purpose
Triclosan 0.3%	Antiseptic
<b>Use</b> for hand-washing to decrease bacteria on the skin	
<b>Warnings</b>	
For external use only	
When using this product	
<ul style="list-style-type: none"> <li>■ do not get into eyes</li> <li>■ if contact occurs, rinse eyes thoroughly with water</li> </ul>	
<b>Stop use and ask doctor if</b>	
<ul style="list-style-type: none"> <li>■ irritation and redness develop</li> </ul>	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>■ wet hands and forearms</li> <li>■ apply 5 milliliters (teaspoonful) or palmful to hands and forearms</li> <li>■ scrub thoroughly for 1 minute and rinse</li> </ul>	
<b>Inactive Ingredients</b> water, sodium laureth sulfate, sodium lauryl sulfate, cocamidopropyl betaine, alcohol denatured, propylene glycol, tetrasodium EDTA, PEG-75, lanolin, boric acid, lauramine oxide, chloroxylenol, methylparaben, propylparaben, fragrance, aloe barbadensis, acid red 1, reactive green 12	

Batch No: 1391 657618P6283.1105

## FRESHANDS

triclosan soap

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76287-576
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	3.0 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
BORIC ACID (UNII: R57ZHV85D4)	
ALCOHOL (UNII: 3K9958V90M)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7H9T)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
LAURAMINE OXIDE (UNII: 4F6FC4M18W)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
EDETATE SODIUM (UNII: MP1J8420LU)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76287-576-06	1 in 1 BOX		
1		800 mL in 1 BAG		
2	NDC:76287-576-17	532 mL in 1 BOTTLE, PLASTIC		
3	NDC:76287-576-24	118 mL in 1 BOTTLE, PLASTIC		
4	NDC:76287-576-01	1200 mL in 1 CARTRIDGE		
5	NDC:76287-576-03	350 mL in 1 CARTRIDGE		
6	NDC:76287-576-05	540 mL in 1 BOTTLE, PLASTIC		
7	NDC:76287-576-07	700 mL in 1 BAG		
8	NDC:76287-576-09	2000 mL in 1 CARTRIDGE		
9	NDC:76287-576-10	1000 mL in 1 CARTRIDGE		
10	NDC:76287-576-11	1000 mL in 1 BOTTLE, PLASTIC		
11	NDC:76287-576-12	1000 mL in 1 BAG		
12	NDC:76287-576-13	800 mL in 1 BAG		
13	NDC:76287-576-14	3785 mL in 1 BOTTLE, PLASTIC		
14	NDC:76287-576-15	946 mL in 1 BOTTLE, PLASTIC		
15	NDC:76287-576-28	149 mL in 1 BOTTLE, PLASTIC		
16	NDC:76287-576-27	800 mL in 1 CARTRIDGE		
17	NDC:76287-576-55	208200 mL in 1 DRUM		
18	NDC:76287-576-08	1 in 1 BOX		
18		1000 mL in 1 BAG		
19	NDC:76287-576-16	236 mL in 1 BOTTLE, PLASTIC		
20	NDC:76287-576-18	50 mL in 1 BOTTLE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/01/2011	

**Labeler** - Spa Concepts, Inc. (609438671)

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

### Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture

Revised: 7/2011

Spa Concepts, Inc.