

SOFTSAN - alcohol lotion
ABC Compounding Co., 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.

SoftSan 6938 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

Ethyl Alcohol 62%

Drug Facts Box OTC-Purpose Section

Antiseptic

Drug Facts Box OTC-Indications & Usage Section

for hand-washing to decrease bacteria on the skin, only when water is not available

Drug Facts Box OTC-Warnings Section

FLAMMABLE, keep away from fire and flames

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

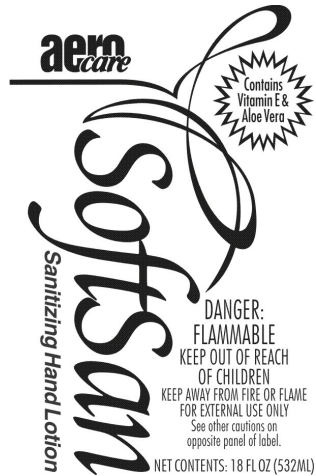
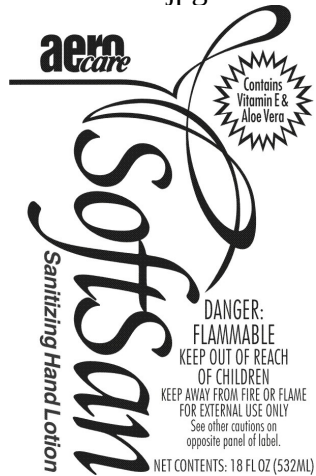
wet hands thoroughly with product and allow to dry without wiping

Drug Facts Box OTC-Inactive Ingredient Section

Water, Cetearyl Isononanoate, Ceteareth-20, Cetearyl Alcohol, Glyceryl Stearate, Glycerin, Ceteareth-12, Cetyl Palmitate, Carbomer, Diisopropylamine, Sodium Styrene/PEG-10 Maleate/Nonoxynol-10 Maleate/Acrylates Copolymer, Methylparaben, Propylparaben, fragrance, Tocopheryl Acetate, Aloe Barbadosis

SoftSan 6938 18oz

693818PA.jpg SoftSan 18oz



Drug Facts	
Active Ingredient Ethyl Alcohol 62%.....	Purpose Antiseptic
Use Use for hand-washing to decrease bacteria on the skin, only when water is not available	
Warnings Flammable, keep away from fire and flames 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 thoroughly with product and allow to dry without wiping 	
Inactive Ingredients Water, Cetearyl Isononanoate, Ceteareth-20, Cetearyl Alcohol, Glyceryl Stearate, Glycerin, Ceteareth-12, Cetyl Palmitate, Carbomer, Diisopropylamine, Sodium Styrene/PEG-10 Maleate/Nonoxynol-10 Maleate/Acrylates Copolymer, Methylparaben, Propylparaben, fragrance, Tocopheryl Acetate, Aloe Barbardensis.	
Batch No: 3500	Manufactured by: ABC Compounding Co., Inc. P. O. Box 16247 Atlanta, GA 30321-0247



SOFTSAN

alcohol lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62257-938
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER 934 (UNII: Z135WT9208)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIISOPROPYLAMINE (UNII: BR9JL140NO)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
CETEARETH-12 (UNII: 7V4MR24V5P)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62257-938-06	1 in 1 BOX		
1		800 mL in 1 BAG		

2	NDC:62257-938-17	532 mL in 1 BOTTLE, PLASTIC		
3	NDC:62257-938-24	118 mL in 1 BOTTLE, PLASTIC		
4	NDC:62257-938-01	1200 mL in 1 CARTRIDGE		
5	NDC:62257-938-03	350 mL in 1 CARTRIDGE		
6	NDC:62257-938-05	540 mL in 1 BOTTLE, PLASTIC		
7	NDC:62257-938-07	700 mL in 1 BAG		
8	NDC:62257-938-09	2000 mL in 1 CARTRIDGE		
9	NDC:62257-938-10	1000 mL in 1 CARTRIDGE		
10	NDC:62257-938-11	1000 mL in 1 BOTTLE, PLASTIC		
11	NDC:62257-938-12	1000 mL in 1 BAG		
12	NDC:62257-938-13	800 mL in 1 BAG		
13	NDC:62257-938-14	3785 mL in 1 BOTTLE, PLASTIC		
14	NDC:62257-938-15	946 mL in 1 BOTTLE, PLASTIC		
15	NDC:62257-938-28	149 mL in 1 BOTTLE, PLASTIC		
16	NDC:62257-938-27	800 mL in 1 CARTRIDGE		
17	NDC:62257-938-55	208200 mL in 1 DRUM		
18	NDC:62257-938-08	1 in 1 BOX		
18		1000 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	12/01/2010	

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

Establishment

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

Revised: 12/2010

ABC Compounding Co., Inc.