INSTI-FOAM SANITIZER - benzethonium chloride liquid Share Corporation

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.

Insti-Foam Sanitizer 6575 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

benzethonium chloride USP 0.2%

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

For external use only

Drug Facts Box OTC-Purpose Section

Antiseptic

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

press pump twice to deliver two squirts (about a quarter size) of foaming product onto the palm of your hand

rub hands together until dry

wash hands with soap and water at earliest opportunity

Drug Facts Box-OTC Inactive Ingredient Section

water, glycerine, dimethicone, DMDM hydantoin, iodopropynl butylcarbamate, fragrance

Insti-Foam Sanitizer 6575 1 gallon

657541S4292.jpg Insti-Foam Sanitizer 1 gallon





INSTI-FOAM SANITIZER

benzethonium chloride liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68654-575

Route of Administration TOPICAL

Active Ingredient/Active Moiety

ı	1.01.00 2.18.0 1.10.10 1.10.10 1.10.10 1.10.10 1.10				
	Ingredient Name	Basis of Strength	Strength		
	BENZETHO NIUM CHLO RIDE (UNII: PH41D05744) (BENZETHONIUM -	BENZETHONIUM	2 mg in 1 mL		
I	UNII:1VU15B70BP)	CHLORIDE	2 mg m i mi		

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
DIMETHICO NE (UNII: 92RU3N3Y1O)				
1,3-DIMETHYLOL-5,5-DIMETHYL-HYDANTO IN (UNII: BYR0546 TOW)				
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68654-575-10	1000 mL in 1 CARTRIDGE		
2	NDC:68654-575-12	1000 mL in 1 BAG		
3	NDC:68654-575-13	800 mL in 1 BAG		
4	NDC:68654-575-14	3785 mL in 1 BOTTLE, PLASTIC		
5	NDC:68654-575-15	946 mL in 1 BOTTLE, PLASTIC		
6	NDC:68654-575-16	236 mL in 1 BOTTLE, PLASTIC		
7	NDC:68654-575-17	532 mL in 1 BOTTLE, PLASTIC		
8	NDC:68654-575-18	50 mL in 1 BOTTLE, PLASTIC		
9	NDC:68654-575-24	115 mL in 1 BOTTLE, PLASTIC		

10 NDC:68654-575-55	208200 mL in 1 DRUM			
BE I C TO C				
Marketing Information				
Marketing Category	Application Number or Monograph (Citation Marketing Start Date	e Marketing End Date	
OTC monograph not final	part333	09/31/2009		

Labeler - Share Corporation (053687356)

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

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

Revised: 2/2010 Share Corporation