INSTI-FOAM SANITIZER- benzalkonium 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.

6457 Insti-Foam Sanitizer Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

benzalkonium chloride USP 0.13%

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, methylchloroisothiazolinone, methylisothiazolinone, fragrance

Insti-Foam Hand Sanitizer





Insti-Foam Hand Sanitizer

INSTI-FOAM SANITIZER

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68654-086
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL	

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
DMDM HYDANTOIN (UNII: BYR0546TOW)				
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)				
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)				
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68654- 086-14	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/09/2022	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	05/09/2022		
	partosse	03/03/2022		

Labeler - Share Corporation (053687356)

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

Establishment					
Name	Address	ID/FEI	Business Operations		
ABC Compounding Co., Inc.		003284353	manufacture(68654-086)		

Revised: 5/2022 Share Corporation