

**CLEAN HANDS INSTANT HAND 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.

Insti-Foam Hand 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, iodopropynyl butylcarbamate, methylchloroisothiazolinone, methylisothiazolinone, fragrance

Insti-Foam Hand Sanitizer

Insti-Foam Sanitizer

KILLS 99.99% OF MOST COMMON GERMS that cause illness in as little as 15 seconds!

- Non-Alcoholic
- Non-Flammable
- Pleasant Fragrance

NET CONTENTS: 1 Gallon (3.8 L)

SHARE CORP

Sold By: Share Corporation • P.O. Box 245013 • Milwaukee, WI 53224 • (800) 776-7192 • www.sharecorp.com

REFILL for bottles with Foam Pump

Drug Facts	
Active Ingredient benzalkonium chloride 0.13%	Purpose Antiseptic
Use for hand-washing to decrease bacteria on the skin, only when water is not available	
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 ■ 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	
Inactive Ingredients water, glycerine, dimethicone, DMDM hydantoin, isodopropyl butylcarbamate, methylchloroisothiazolinone, methylisothiazolinone, fragrance	

1263.031020

Insti-Foam Hand Sanitizer

CLEAN HANDS INSTANT HAND SANITIZER

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68654-457
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 BUTYL CARBAMATE (UNII: 603P14DHEB)	
METHYLCHLOROISO THIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISO THIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68654-457-10	1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	03/17/2020	
2	NDC:68654-457-12	1000 mL in 1 BAG; Type 0: Not a Combination Product	03/17/2020	
3	NDC:68654-457-	900 mL in 1 BAG; Type 0: Not a Combination Product	03/17/2020	

3	13	500 mL in 1 BAG, Type 0: Not a Combination Product	03/17/2020	
4	NDC:68654-457-18	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/17/2020	
5	NDC:68654-457-27	800 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	03/17/2020	
6	NDC:68654-457-14	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/17/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/17/2020	

Labeler - Share Corporation (053687356)

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

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(68654-457)

Revised: 3/2020

Share Corporation