FOAMING INSTANT HAND SANITIZER- benzealkonium chloride liquid Pro Source Distributors, 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.

Foaming Instant Hand Sanitizer 6457

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

Foaming Instant Hand Sanitizer 6457

PACKAGED FOR USE IN A
WALL MOUNT
DISPENSER

Foaming Instant Hand Sanitizer

Kills 99.9% of most common germs that cause illness in as little as 15 seconds



Non-Alcohol
 Non-Flammable
 Pleasant Fragrance

Drug Facts

Active Ingredient

Purpose

benzalkonium chloride 0.13%

..... 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

- do not get into eyes
- if contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor if

■ 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, iodopropynyl butylcarbamate, methylchloroisothiazolinone, methylisothiazolinone, fragrance

6457M7L100292.010719

Sold By: Pro-Source Distributors, Inc. 2613 - 11th Street, Rockford, IL 61109 815-229-9555 • WWW.PDI1SUPPLY.COM

Net Contents: 1000 ML 33.8 OZ

FOAMING INSTANT HAND SANITIZER

benzealkonium chloride liquid

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72234-457
--------------	----------------	--------------------	---------------

Route of Administration TOPICAL

Active Ingredient/Active Moiety

п	· · · · · · · · · · · · · · · · · · ·		
I	Ingredient Name	Basis of Strength	Strength
I	BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKONIUM -	BENZALKONIUM	1.3 mg
ı	UNII:7N6JUD5X6Y)	CHLORIDE	in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
DMDM HYDANTO IN (UNII: BYR0546TOW)		
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)		
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)		
METHYLISO THIAZO LINO NE (UNII: 229 D0 E1QFA)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72234-457- 10	1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	0 2/0 4/20 19	
2	NDC:72234-457- 18	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/04/2019	
3	NDC:72234-457- 14	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/04/2019	
4	NDC:72234-457- 12	1000 mL in 1 BAG; Type 0: Not a Combination Product	02/04/2019	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	05/29/2018		

Labeler - Pro Source Distributors, Inc. (837372085)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
ABC Compounding Co., Inc.		003284353	manufacture (72234-457)	

Revised: 2/2019 Pro Source Distributors, Inc.