SANI-FOAM INSTANT HAND SANITIZER - benzethonium chloride liquid General Products & Supply, 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.

Sani-Foam Instant Hand 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

Sani-Foam Instant Hand Sanitizer 6575 18 oz

657518P46462.jpg Sani-Foam Instant Hand Sanitizer 18 oz





Drug Facts

Active Ingredient

benzethonium chloride USP 0.2%

Purpose

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 hands with soap and water at earliest opportunity

Inactive Ingredients water, glycerine, dimethicone, DMDM hydantoin, iodopropynyl butylcarbamate, fragrance

SANI-FOAM INSTANT HAND SANITIZER

benzethonium chloride liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68609-575

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Basis of Strength Ingredient Name Strength BENZETHO NIUM CHLO RIDE (UNII: PH41D05744) (BENZETHO NIUM -BENZETHONIUM 2 mg in 1 mL UNII:1VU15B70BP) **CHLORIDE**

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:68609-575-10	1000 mL in 1 CARTRIDGE			
2	NDC:68609-575-12	1000 mL in 1 BAG			
3	NDC:68609-575-13	800 mL in 1 BAG			
4	NDC:68609-575-14	3785 mL in 1 BOTTLE, PLASTIC			
5	NDC:68609-575-15	946 mL in 1 BOTTLE, PLASTIC			
6	NDC:68609-575-16	236 mL in 1 BOTTLE, PLASTIC			
7	NDC:68609-575-17	532 mL in 1 BOTTLE, PLASTIC			
8	NDC:68609-575-18	50 mL in 1 BOTTLE, PLASTIC			
9	NDC:68609-575-24	115 mL in 1 BOTTLE, PLASTIC			
10	NDC:68609-575-55	208200 mL in 1 DRUM			

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333	01/31/2004				

Labeler - General Products & Supply, Inc. (085524155)

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

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

Revised: 2/2010 General Products & Supply, Inc.