SANIFOAM - alcohol aerosol, foam Genesan Systems

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.

SaniFoam 4773 Drug Facts and Label

Drug Facts Box OTC-Active Ingredients Section

Ethyl Alcohol 62%

Drug Facts Box OTC-Purpose Section

Antiseptic

Drug Facts Box OTC-Indications and Usage Section

for hand-washing to decrease bacteria on the skin, only when water is not available

Drug Facts Box OTC-Warnings Section

Flammable, keep away from fire and flames

For external use only

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

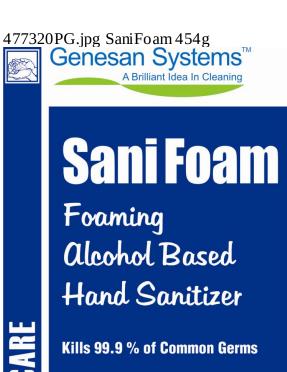
press valve once to deliver one squirt (about a quarter size) of foaming product onto the palm of your hand

rub hands together and allow to dry without wiping

Drug Facts Box OTC-Inactive Ingredients Section

water, DEA-C8-18 perfluoroalkylethyl phosphate, cetearyl alcohol, polysorbate 65, dimethicone PEG-8 meadowfoamate, meadowfoamamidopropyl betaine, butane, propane, fragrance

SaniFoam 4773 454g





Disinfectante espumoso paramanos con base de alcohol

NET WT. 16 0Z (454 grams)

WARNING: FLAMMABLE

CONTENTS UNDER PRESSURE KEEP OUT OF REACH OF CHILDREN

Do not puncture or incinerate. Do not store near fire or flame.

Do not expose to temperatures above 125°F.

Avoid contact with eyes. Use only according to label directions.

Call Regional Poison Control Center for
further assistance if necessary.

Drug Facts

Active Ingredient

Purpose

Ethyl Alcohol 62%

....Antiseptic

Use for hand-washing to decrease bacteria on the skin, only when water is not available

Warnings

Flammable, keep away from fire and flames 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

Directions ■ press valve once to deliver one squirt (about a quarter size) of foaming product onto the palm of your hand ■ rub hands together and allow to dry without wiping

Inactive Ingredients water, DEA-C8-18 perfluoroalkylethyl phosphate, cetearyl alcohol, polysorbate 65, dimethicone PEG-8 meadowfoamate, meadowfoamamidopropyl betaine, butane, propane, fragrance



Batch No.: Reorder: 900116

SANIFOAM

alcohol aerosol, foam

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:52030-773

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII: 3K9958 V90M)	ALCOHOL	620 mg in 1 g
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Inactive Ingredients	
Ingredient Name	Strength
PROPANE (UNII: T75W9911L6)	
BUTANE (UNII: 6LV4FOR43R)	
WATER (UNII: 059QF0KO0R)	

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52030-773-25	199 g in 1 CAN		
2	NDC:52030-773-26	454 g in 1 CAN		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333	0 1/0 1/20 10	

Labeler - Genesan Systems (961574576)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
ABC Compounding Company of Texas, Inc.		026219253	manufacture	

Revised: 3/2010 Genesan Systems