FOAMFRESH ALCO-FREE HAND SANITIZER- benzalkonium chloride liquid
Woodbine Products Company

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.

Drug Facts

Active Ingredient

Benzalkonium Chloride 0.1%

Purpose

Antimicrobial

Uses:

For hand sanitizing to decrease bacteria on the skin.

Recommended for repeated use.

Warnings:

For external use only

When using this product avoid contact with eyes.

In case of eye contact, flush eyes with water.

Stop use and ask a doctor if irritation or redness develops, or if conditions persists for more than 72 hours.

Keep out of reach of children.

Children must be supervised in use of this product.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

Pump a small amount of foam into palm of hand.

Rub thoroughly over all surfaces of both hands.

Rub hands together briskly until dry.

Inactive Ingredients:

Water, Cetrimonium Chloride, Laurtrimonium Chloride, Dihydroxyethyl Cocamine Oxide, Glycereth-17 Cocoate, Citric Acid, Fragrance.

FoamFresh

Alco-Free Hand Sanitizer

Formulated to reduce the number of germs on the hands that can cause infection and illness

Alcohol free, so it can be used in any area without fear of it creating a flammable

atmosphere

Use on clean, non-soiled hands any time when rinsing with water is not available

Kills 99.99% of common germs that can cause disease

PK

Woodbine Products Company

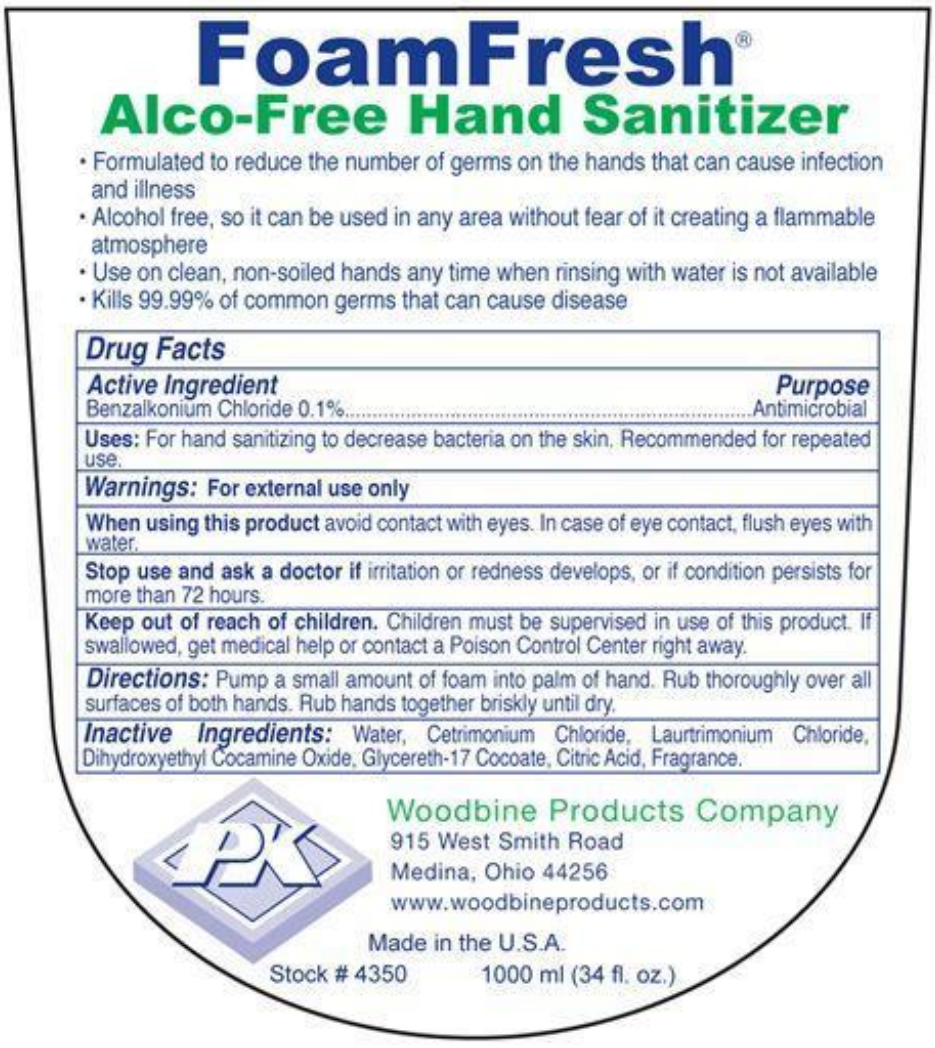
915 West Smith Road

Medina, Ohio 44256

wwww.woodbineproducts.com

Made in the U.S.A.

Stock # 4350 1000 ml (34 fl. oz.)



FOAMFRESH ALCO-FREE HAND SANITIZER

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11429-1001

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
LAURTRIMONIUM CHLORIDE (UNII: A81MSI0FIC)	
DIHYDROXYETHYL COCAMINE OXIDE (UNII: 8AR51R3BL5)	
GLYCERETH-17 COCOATE (UNII: 3057VPT0KC)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11429-1001-2	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/16/2018	
2	NDC:11429-1001-3	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/16/2018	
3	NDC:11429-1001-4	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/16/2018	
4	NDC:11429-1001-7	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/16/2018	
5	NDC:11429-1001-8	1250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/16/2018	
6	NDC:11429-1001-9	1100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/16/2014	
7	NDC:11429-1001-0	1125 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/16/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/16/2014	

Labeler - Woodbine Products Company (004220323)

Establishment

Name	Address	ID/FEI	Business Operations
Woodbine Products Company		004220323	manufacture(11429-1001)