

FOAMFRESH ALCO-FOAM HAND SANITIZER - alcohol 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

Ethyl Alcohol 62% v/v

Purpose

Antimicrobial

Uses:

For hand sanitizing to decrease bacteria on the skin that could cause disease.

Recommended for repeated use.

Warnings:

Flammable. Keep away from fire or flame

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 condition persists for more than 72 hours.

Keep out of reach of children.

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

Directions:

Place enough product in your palm to thoroughly cover your hands.

Rub hands together briskly until dry.

Children under 6 years of age should be supervised when using this product.

Other information:

Store below 110 F (43 C).

May discolor certain fabrics or surfaces.

Inactive ingredients:

Water, DEA-C8-18 Perfluoroalkylethyl Phosphate

Alco-Foam

Hand Sanitizer

Decreases common germs that can cause illness. Leaves skin soft and refreshed.

Woodbine Products Company

915 West Smith Road

Medina, Ohio 44256

www.woodbineproducts.com

Made in the USA

Stock # 4640 900 ml (31 fl. oz.)

FoamFresh Alco-Foam

Sanitizer

Alco-Foam Hand Sanitizer

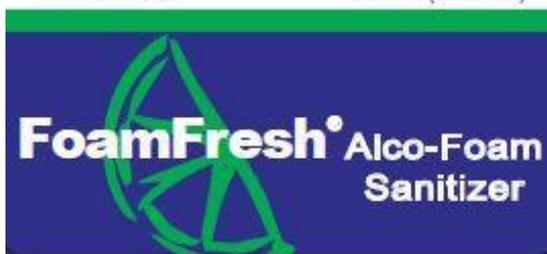
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alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11429-1004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	62 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0K00R)				
DIETHANOLAMINE BIS(C8-C18 PERFLUOROALKYLETHYL)PHOSPHATE (UNII: 4J55VM509S)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11429-1004-1	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/19/2018	
2	NDC:11429-1004-2	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/19/2018	
3	NDC:11429-1004-3	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/19/2018	
4	NDC:11429-1004-4	900 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/19/2018	
5	NDC:11429-1004-5	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/19/2018	
6	NDC:11429-1004-6	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/19/2018	
7	NDC:11429-1004-7	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/19/2018	
8	NDC:11429-1004-8	1250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/19/2018	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/31/2014		

Labeler - Woodbine Products Company (004220323)

Establishment

Name	Address	ID/FEI	Business Operations
Woodbine Products Company		004220323	manufacture(11429-1004)

Revised: 11/2018

Woodbine Products Company