ALCO HAND SANITIZER- alcohol gel 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 1003

Active Ingredient

Ethyl Alcohol 70% v/v

Purpose

Sanitizer

Uses:

For hand sanitizing to decrease bacteria on the skin.

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:

Apply gel to dry hands and rub thoroughly until hands are dry.

Do not rinse or wipe gel off.

Should solution enter eyes, rinse immediately with water.

Other Information:

Store below 110 F (43 C).

May discolor certain fabrics or surfaces.

Inactive Ingredients:

Water, Propylene Glycol, PEG-33 (and) PEG-8 Dimethicone (and) PEG-14, Triethanolamine, Carbopol and Fragrance.

Alco-Gel Hand Sanitizer

Evaporates quickly

Kills 99.99% of common germs that can cause illness

Leaves hands smooth and refreshed

PK

Woodbine Products Company

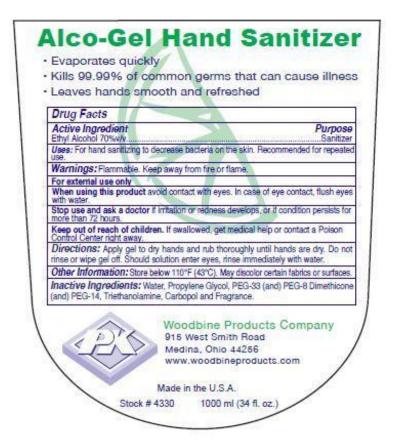
915 West Smith Road

Medina, Ohio 44256

www.woodbineproducts.com

Made in the U.S.A.

Stock # 4330 10000 ml (34 fl. oz.)



ALCO HAND SANITIZER

alcohol gel

Product Information				
HUMAN OTC DRUG	Item Code (Source)	NDC:11429-1003		
TOPICAL				

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
POLYETHYLENE GLYCOL 700 (UNII: 762678AC5R)		
TROLAMINE (UNII: 903K93S3TK)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11429- 1003-1	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/19/2018	
2	NDC:11429- 1003-3	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/19/2018	
3	NDC:11429- 1003-4	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/19/2018	
4	NDC:11429- 1003-7	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/19/2018	
5	NDC:11429- 1003-8	1250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/19/2018	
6	NDC:11429- 1003-5	1892 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/13/2020	
7	NDC:11429- 1003-6	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/13/2020	
8	NDC:11429- 1003-2	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2014	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/10/2014	

Labeler - Woodbine Products Company (004220323)

Establishment				
Name	Address	ID/FEI	Business Operations	
Woodbine Products Company		004220323	manufacture(11429-1003)	