ALCOHOL BASED FOAMING HAND SANITIZER- ethyl alcohol hand sanitizer liquid National Chemical Laboratories, 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.

Alcohol Based Foaming Hand Sanitizer

Active Ingredient(s)

Ethyl Alcohol 70% v/v. Purpose: Antiseptic, Antimicrobial Alcohol Based Foaming Hand Sanitizer Approval Label







Antiseptic, Hand Sanitizer, Antimicrobial

See Image "Alcohol Based Foaming Hand Sanitizer Approval Label"

Use

- Hand sanitizing to help reduce microorganisms on the skin Recommended for repeated use
- Use this product when soap and water are not available Do not use when hands are visibly soiled

See "Alcohol Based Foaming Hand Sanitizer FDA Approval Label"

Warnings

For external use only.

FLAMMABLE. Keep away from fire or flame, heat, sparks and sources of static discharge.

See "Alcohol Based Foaming Hand Sanitizer FDA Approval Label"

Do Not Use

- Stop use if irritation or redness develops, if condition persist for more than 72 hours consult a physician.
- See "Alcohol Based Foaming Hand Sanitizer FDA Approval Label"

When using this product avoid contact with eyes. In case of eye contact, rinse eyes thoroughly with water.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

See "Alcohol Based Foaming Hand Sanitizer FDA Approval Label"

Stop use if irritation or redness develops, if condition persist for more than 72 hours consult a physician.

See "Alcohol Based Foaming Hand Sanitizer FDA Approval Label"

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

See "Alcohol Based Foaming Hand Sanitizer FDA Approval Label"

Directions

- Apply sufficient product in your palm to cover hands and rub hands together briskly until dry.
 - For children under six years of age, hand sanitizer should only be used with adult supervision.
- See "Alcohol Based Foaming Hand Sanitizer FDA Approval Label"

Other information

- FLAMMABLE. Keep away from fire or flame, heat, sparks and sources of static discharge.
- See "Alcohol Based Foaming Hand Sanitizer FDA Approval Label"

Inactive ingredients

Cocamidopropyl PG-Dimonium Chloride Phosphate, Denatonium benzoate, Dimethicone PEG-7 Phosphate, PEG-8 Dimethicone, PEG-10 Dimethicone, tert-Butyl alcohol, Water

See "Alcohol Based Foaming Hand Sanitizer FDA Approval Label"

Package Label - Principal Display Panel

1000 ml NDC: 71023-440-57

See "Alcohol Based Foaming Hand Sanitizer FDA Approval Label"







ethyl alcohol hand sanitizer liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71023-440

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
PEG-8 DIMETHICONE (UNII: GIA7T764OD)		
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)		
DIMETHICONE PEG-7 PHOSPHATE (UNII: WTP86Y84TV)		
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)		
COCAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: H2KVQ74JM4)		
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)		
WATER (UNII: 059QF0KO0R)		

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:71023-440- 57	1000 mL in 1 BAG; Type 0: Not a Combination Product	02/15/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	02/15/2021	

Labeler - National Chemical Laboratories, Inc. (002289619)

Registrant - National Chemical Laboratories, Inc. (002289619)

Establishment			
Name	Address	ID/FEI	Business Operations
National Chemical Laboratories, Inc.		002289619	manufacture(71023-440)