

HYDRO- alcohol gel
HYDRO GLOBAL 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.

Active Ingredient(s)

Ethyl Alcohol 70% v/vAntimicrobial

Purpose

Antimicrobial, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)

Inactive ingredients

Water, Triethanolamine, Carbomer, Aloe Vera Extract, Phenoxethynol

Package Label - Principal Display Panel

HYDRO Hand Sanitizer Gel with Aloe

8.5 OZ (250 mL)



Drug Facts	
Active Ingredients Ethyl Alcohol 70% v/v.....	Purpose Antimicrobial
Use[s] Hand sanitizer to help reduce bacteria that can potentially cause disease.	
Warnings For external use only. Flammable. Keep away from heat or flame.	
Do not use ■ in children less than 2 months of age ■ on open skin wounds	
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions ■ Place enough product on hands to cover all surfaces. Rub hands together until dry. ■ Supervise children under 6 years of age when using this product to avoid swallowing.	
Inactive Ingredients Water, Triethanolamine, Carbomer, Aloe Vera Extract, Phenoxethynol	

Distributed by Hydro Global, Inc.
Las Vegas, NV 89103
www.HydroGlobalInc.com
1-800-770-1275
6 82863 33970 3

HYDRO

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77994-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.0003 mL in 1 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.001 mL in 1 mL
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.002 mL in 1 mL
WATER (UNII: 059QF0KO0R)	0.4 mL in 1 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.0025 mCi in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77994-100-01	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2020	

Labeler - HYDRO GLOBAL INC (117523372)

Establishment

Name	Address	ID/FEI	Business Operations
Aloe Laboratories, Inc		606458024	repack(77994-100)

Establishment

Name	Address	ID/FEI	Business Operations
Chemical Solutions de México, S.A. de C.V.		813291820	manufacture(77994-100)

Revised: 7/2020

HYDRO GLOBAL INC