HAND SANITIZER GEL- alcohol gel Solvents and Petroleum Service, 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 Ingredients



Alcohol

Purpose

Antiseptic, Hand Sanitizer



Use

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

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

Warnings

WARNINGS - FOR EXTERNAL USE ONLY - HANDS. FLAMMABLE. KEEP AWAY FROM HEAT AND FLAME.

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

Do not use

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. Do not use on children less than 2 months of age. Do not use on open wounds.

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

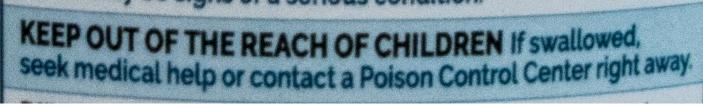
WHEN USING THIS PRODUCT keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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.

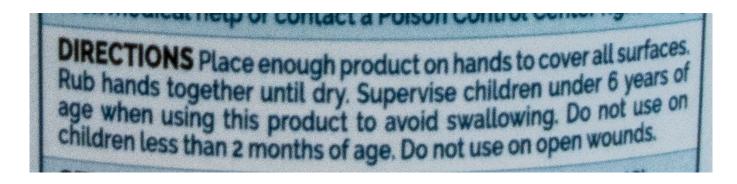
STOP USE AND ASK A DOCTOR if irritation or rash occurs. These may be signs of a serious condition.

Keep OUT OF THE REACH OF CHILDREN



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

Directions



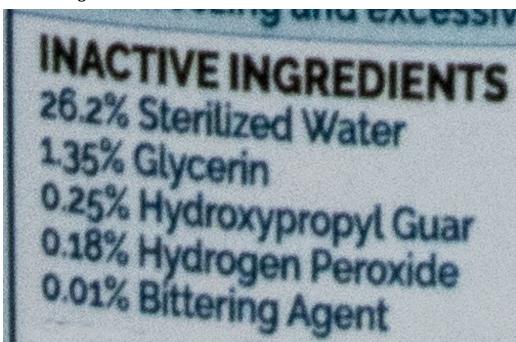
- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

OTHER INFORMATION Store between 59 - 86°F (15 - 30°C).
Avoid freezing and excessive heat above 104°F (40°C).

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients



glycerin, hydrogen

Package Label - Principal Display Panel

ACTIVE INGREDIENTS

PURPOSE

72% Ethyl Alcohol*

ANTISEPTIC

USES 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 - HANDS.
FLAMMABLE. KEEP AWAY FROM HEAT AND FLAME.

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 THE REACH OF CHILDREN If swallowed, seek 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. Do not use on children less than 2 months of age. Do not use on open wounds.

OTHER INFORMATION Store between 59 - 86°F (15 - 30°C). Avoid freezing and excessive heat above 104°F (40°C).

INACTIVE INGREDIENTS

26.2% Sterilized Water

1.35% Glycerin

0.25% Hydroxypropyl Guar

0.18% Hydrogen Peroxide

0.01% Bittering Agent

*Effective at eliminating more than 99.99% of many common harmful germs and bacteria in as little as 15 seconds.



Manufactured by Clean All, Syracuse, NY

HAND SANITIZER GEL

alcohol gel

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:75660-002

Route of Administration TOPICAL

Active Ingredient/Active Moiety

	Ingredient Name	Basis of Strength	Strength
ı	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	72 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
DENATO NIUM BENZO ATE (UNII: 4YK5Z54AT2)	0.01 mL in 100 mL	
GLYCERIN (UNII: PDC6A3C0OX)	1.35 mL in 100 mL	
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.18 mL in 100 mL	
WATER (UNII: 059QF0KO0R)	26.2 mL in 100 mL	
HYDROXYPROPYL GUAR (2500-4500 MPA.S AT 1%) (UNII: 3A1I7376TC)	0.25 mL in 100 mL	

Packaging

П				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:75660-002- 01	1 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 - Solvents and Petroleum Service, Inc. (013277454)

Registrant - Solvents and Petroleum Service, Inc. (013277454)

Establishment			
Name	Address	ID/FEI	Business Operations
Clean All		117505240	manufacture(75660-002), repack(75660-002)

Revised: 6/2020 Solvents and Petroleum Service, Inc.