HAND SANITIZER- alcohol gel
PakLab

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 62% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease.

Warnings

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

When using this product avoid contact with face, eyes, and broken skin. If eyes contact occurs, flush thoroughly with water and seek medical advice.

Stop use and ask a doctor if irritation or rash occurs.

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 and redness develops.

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

Directions

- Wet hand thoroughly with product and rub into skin until dry.
- Children under 6 years of age should be supervised by an adult when using this product.

Inactive ingredients

aqua (water, eau), propylene glycol, glycerin, carbomer, aminomethyl propanol, isopropyl myristate, t-butyl alcohol

Package Label - Principal Display Panel

221 mL NDC: 61531-389-01

HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61531-389
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**
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 100 mL
2-(1-CHLOROCYCLOPROPYL)-3-(2-CHLOROPHENYL)-1,2-PROPANEDIOL (UNII: SJ211700DZ)	0.5 mL in 100 mL

WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61531-389-01	221 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - PakLab (790530976)

Registrant - PakLab (790530976)

Establishment

Name	Address	ID/FEI	Business Operations
PakLab		790530976	manufacture(61531-389) , label(61531-389) , pack(61531-389)

Revised: 11/2020 PakLab