HAND SANITIZER- alcohol liquid
The Lab LLC

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.

Hand Sanitizer

This is a hand sanitizer manufactured per guidance outlined in the final ruling of 21 CFR Part 310- Safety and Effectiveness of Consumer Antiseptic Rubs; Topical Antimicrobial Drug Products for Over-the-Counter Human Use. The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation):

a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v))
b. Glycerin 98% (0.015% v/v).
c. Hydrogen peroxide 3% (0.04% v/v).
d. Sterile distilled water or boiled cold water (19.9% v/v).
e. Acrylates Copolymer (rheology modifier) (0.05% v/v).
f. Triethanolamine (pH neutralizer) (0.005% v/v).

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

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. 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 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.

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Directions

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

Other information

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

Inactive ingredients

Purified water USP, acrylates copolymer, hydrogen peroxide, glycerin, triethanolamine

Package Label - Principal Display Panel

HAND SANITIZER

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:74184-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
TRIETHANOLAMINE TRIS(DIHYDROGEN PHOSPHATE) (UNII: 36YHT392ID)	0.005 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.015 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.04 mL in 100 mL
WATER (UNII: 059QF0KO0R)	19.9 mL in 100 mL
PEG-10 ACRYLATE/PERFLUOROHEXYLETHYL ACRYLATE COPOLYMER (UNII: D76Z87928N)	0.05 mL in 100 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:74184-001-15	3785 mL in 1 JUG; Type 0: Not a Combination Product	05/06/2020	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC monograph not final	part333A	05/06/2020	

Labeler - The Lab LLC (092838384)

Establishment			
Name	**Address**	**ID/FEI**	**Business Operations**
The Lab LLC		092838384	manufacture(74184-001)

Revised: 8/2020

The Lab LLC