

ACCURATE LABS ANTISEPTIC HAND SANITIZER- ethyl alcohol liquid
Accurate Labs, 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.

ACCURATE LABS ANTISEPTIC HAND SANITIZER

Drug Facts

Active ingredient

Ethyl alcohol 80% v/v

Purpose

Antiseptic

Uses

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flame
For external use only

Do not use • in children less than 2 months of age • on open skin wounds

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

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

Directions

- wet hands thoroughly with product and allow to dry without wiping
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

- store between 20-25°C (68-77°F)
- avoid freezing and excessive heat above 40°C (104°F)
- may discolor certain fabrics

Inactive ingredients

d-limonene, glycerin, water

Questions?

1-800-484-1699

You may also report serious side effects to this phone number.

Mon-Fri 9:00 AM - 5:00 PM

Alcohol Antiseptic 80%***Topical Solution******Non-Sterile Solution***

Manufactured for: Accurate Labs, LLC
301W 50th St, Odessa, TX 79764

Packaging



ANTISEPTIC HAND SANITIZER

Alcohol Antiseptic 80%
Topical Solution
Non-Sterile Solution

8 fl oz (236 mL)

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Drug Facts (continued)

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Lot No :

Expiry:



ACCURATE LABS ANTISEPTIC HAND SANITIZER

ethyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78434-110
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 L in 100 L

Inactive Ingredients

Ingredient Name	Strength
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78434-110-02	0.059 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/01/2020	06/30/2025
2	NDC:78434-110-04	0.118 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/01/2020	06/30/2025
3	NDC:78434-110-08	0.236 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/01/2020	06/30/2025
4	NDC:78434-110-16	0.473 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/01/2020	06/30/2025
5	NDC:78434-110-32	0.946 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/01/2020	06/30/2025
6	NDC:78434-110-64	1.89 L in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	06/30/2025
7	NDC:78434-110-70	3.79 L in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	06/30/2025
8	NDC:78434-110-75	9.46 L in 1 CONTAINER; Type 0: Not a Combination Product	06/01/2020	06/30/2025
9	NDC:78434-110-80	18.93 L in 1 CONTAINER; Type 0: Not a Combination Product	06/01/2020	06/30/2025
10	NDC:78434-110-85	208.2 L in 1 CONTAINER; Type 0: Not a Combination Product	06/01/2020	06/30/2025
11	NDC:78434-110-90	1211.3 L in 1 CONTAINER; Type 0: Not a Combination Product	06/01/2020	06/30/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2020	06/30/2025

Labeler - Accurate Labs, LLC (113427259)

Establishment

Name	Address	ID/FEI	Business Operations
Accurate Labs, LLC		113427259	manufacture(78434-110)

Revised: 10/2021

Accurate Labs, LLC