SIMPURITY HAND SANITIZER- alcohol gel
Truesdell Manufacturing & Consulting, 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.

Simpurity Hand Sanitizer, 4 oz.

Simpurity 75% alcohol Hand Sanitizer

This is a hand sanitizer manufactured according to the 1994 tentative final monograph for consumer antiseptics.

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) (75%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
b. hydroxyethylcellulose
c. aloe powder
d. propylene glycol
e. hyaluronic acid
f. tea tree essential oil
g. vitamin E
h. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. The product has undergone finished formulation product testing (kill study) to confirm effifacy and safety.

Active Ingredient(s)

Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Uses

Helps reduce bacteria on the skin 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.

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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)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

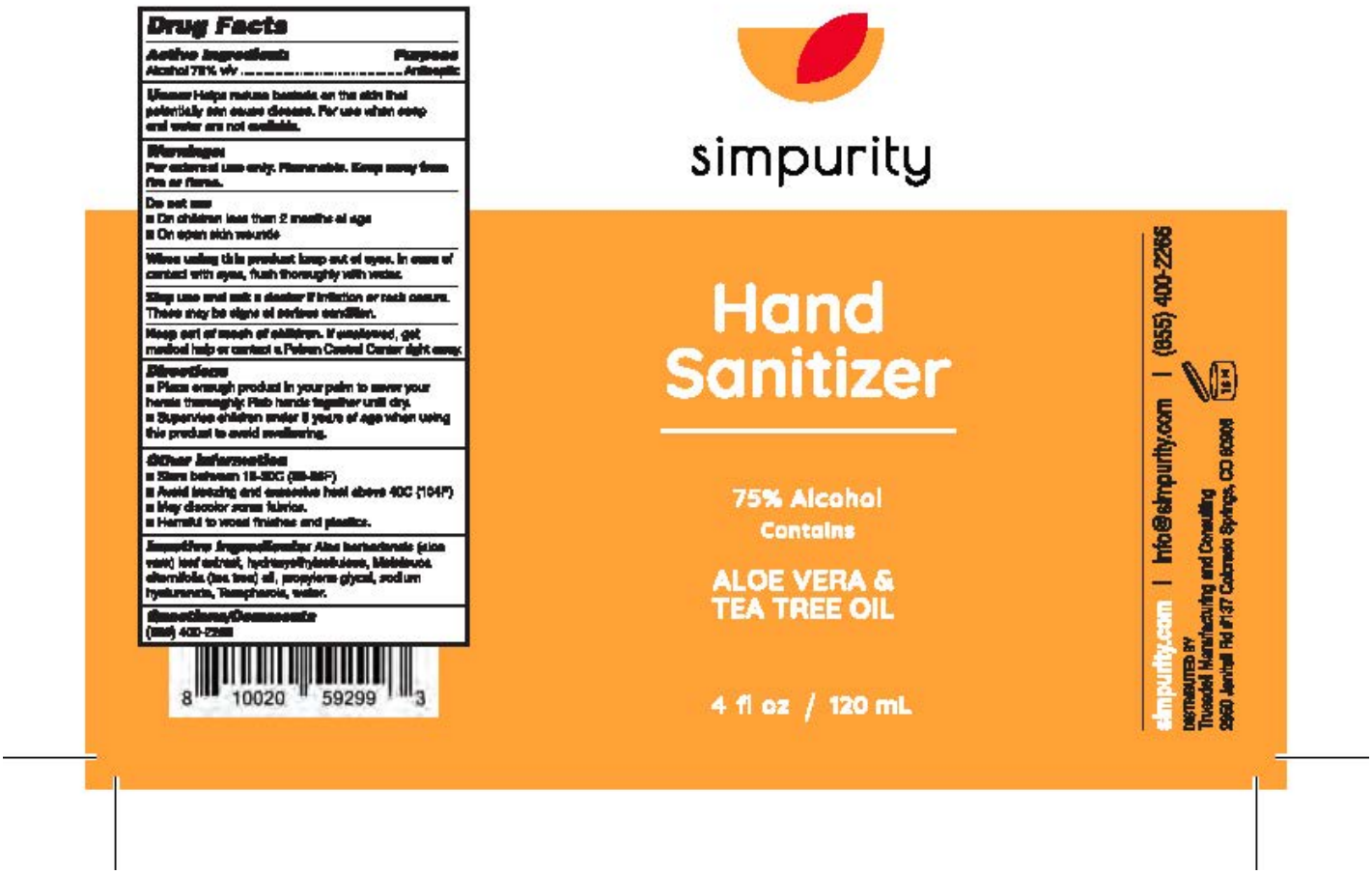
distilled water
hydroxyethylcellulose
aloe powder
propylene glycol
hyaluronic acid
tea tree essential oil
vitamin E

74069-002-08 240 mL Package Label - Principal Display Panel

240 mL NDC: 074069-002-08

74069-002-04 Principal Display Panel

120 mL NDC: 074069-002-04



SIMPURITY HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:74069-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
TOCOPHEROL (UNII: R0ZB2556P8)	0.25 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.25 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	2 mL in 100 mL
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	0.59 mL in 100 mL
WATER (UNII: 059QF0KO0R)	21.65 mL in 100 mL

HYALURONATE SODIUM (UNII: YSE9PPT4TH)	0.01 mL in 100 mL
TEA TREE OIL (UNII: VIF565UC2G)	0.25 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74069-002-08	240 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	05/04/2020	
2	NDC:74069-002-04	120 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	05/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/04/2020	

Labeler - Truesdell Manufacturing & Consulting, LLC (117238763)

Revised: 12/2021 Truesdell Manufacturing & Consulting, LLC