

**LOFT AND BEAR HAND WASH 4 OZ. WITH ETHANOL ALCOHOL- alcohol liquid  
Y. SA, 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.*

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**Loft and Bear Hand Wash with Ethanol Alcohol**

This is a hand sanitizer. f Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, 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. Tea Tree Oil (0.125% v/v).
- c. Aloe Vera Leaf (0.1% v/v).
- d. Lemon Oil (0.0625% v/v).
- e. Sterile distilled water or boiled cold water.

**Active Ingredient(s)**

Alcohol 70% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

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 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.

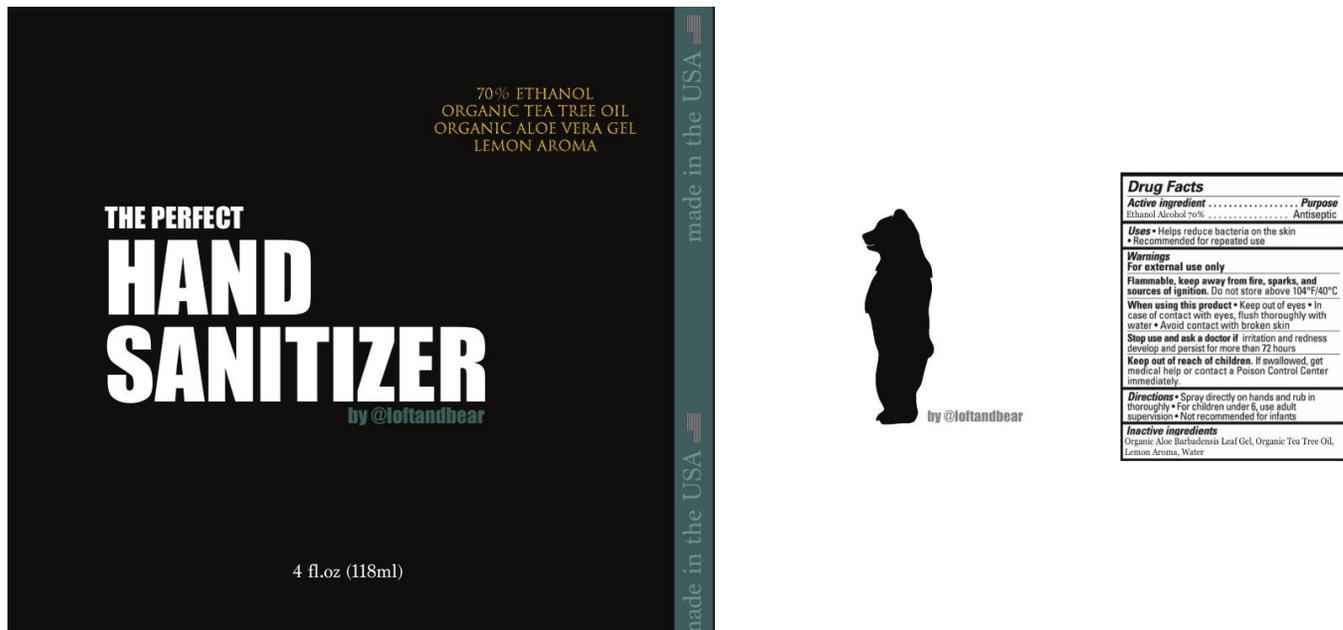
**Other information**

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

**Inactive ingredients**

aloe vera leaf, tea tree oil, lemon oil, purified water USP

**Package Label - Principal Display Panel**



118.3 mL NDC: 77179-7004-3

LOFT AND BEAR HAND WASH 4 OZ. WITH ETHANOL ALCOHOL			
alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77179-7004
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	118.3 mL in 118.3 mL	
Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)	118.3 mL in 118.3 mL		
LEMON OIL (UNII: I9GRO824LL)	118.3 mL in 118.3 mL		

TEA TREE OIL (UNII: VIF565UC2G)	118.3 mL in 118.3 mL
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**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77179-7004-3	118.3 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 - Y. SA, INC (080269381)**

**Establishment**

Name	Address	ID/FEI	Business Operations
Y. SA, INC		080269381	manufacture(77179-7004)

Revised: 6/2020

Y. SA, INC