LOFT AND BEAR HAND WASH WITH ETHANOL ALCOHOL 16 OZ- alcohol liquid
LOFT AND BEAR HAND WASH WITH ETHANOL ALCOHOL 128 OZ/ 1 GALLON- alcohol liquid
LOFT AND BEAR HAND WASH WITH ETHANOL ALCOHOL 8 OZ- 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.

Loft and Bear Hand Wash with Ethanol Alcohol

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) (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. Sterile distilled water (26.5% v/v).
c. Aloe Barbadensis Leaf liquid (3.2% v/v).
d. Tea Tree Oil (0.3% v/v)

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.

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.

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.

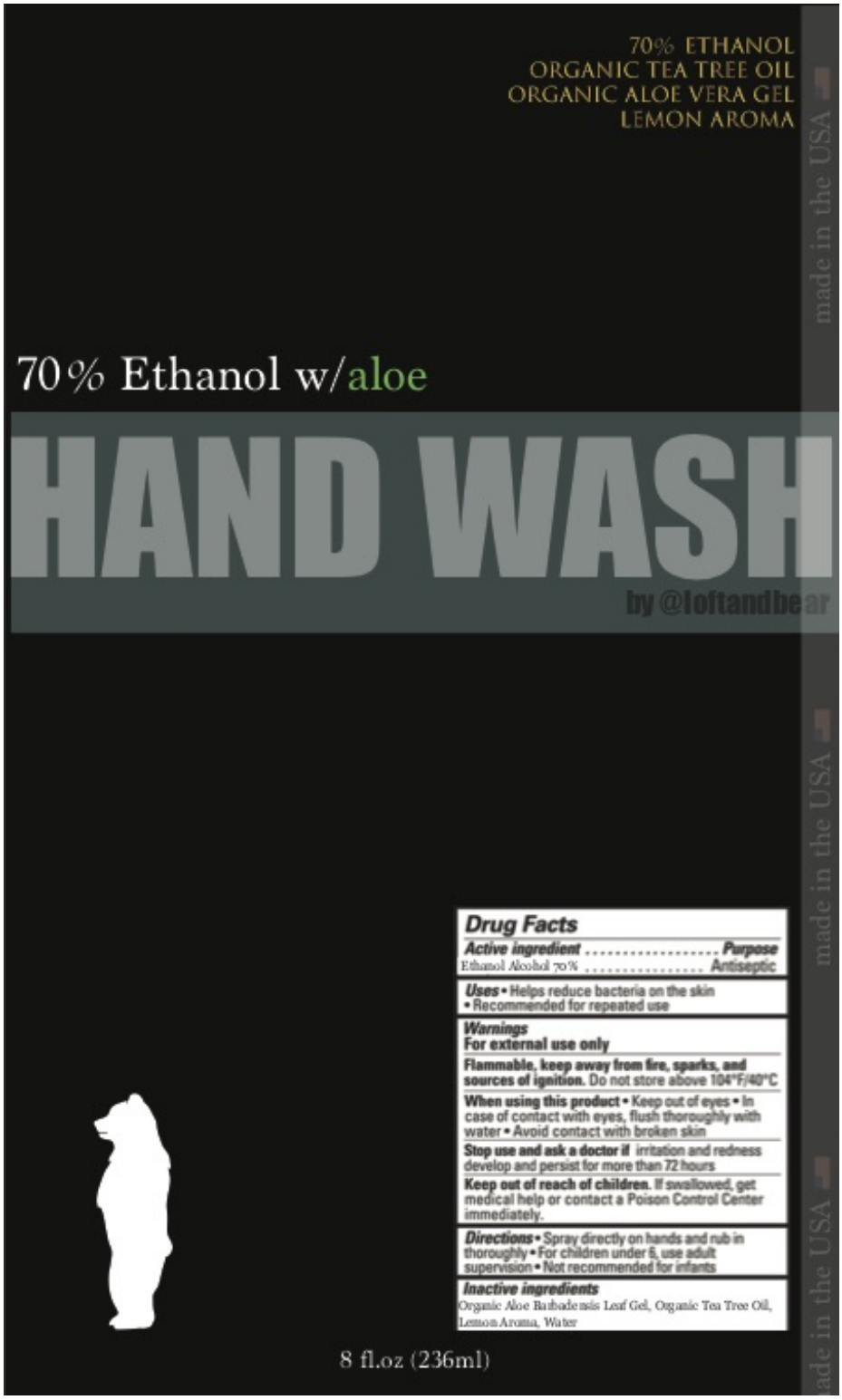
Other information

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

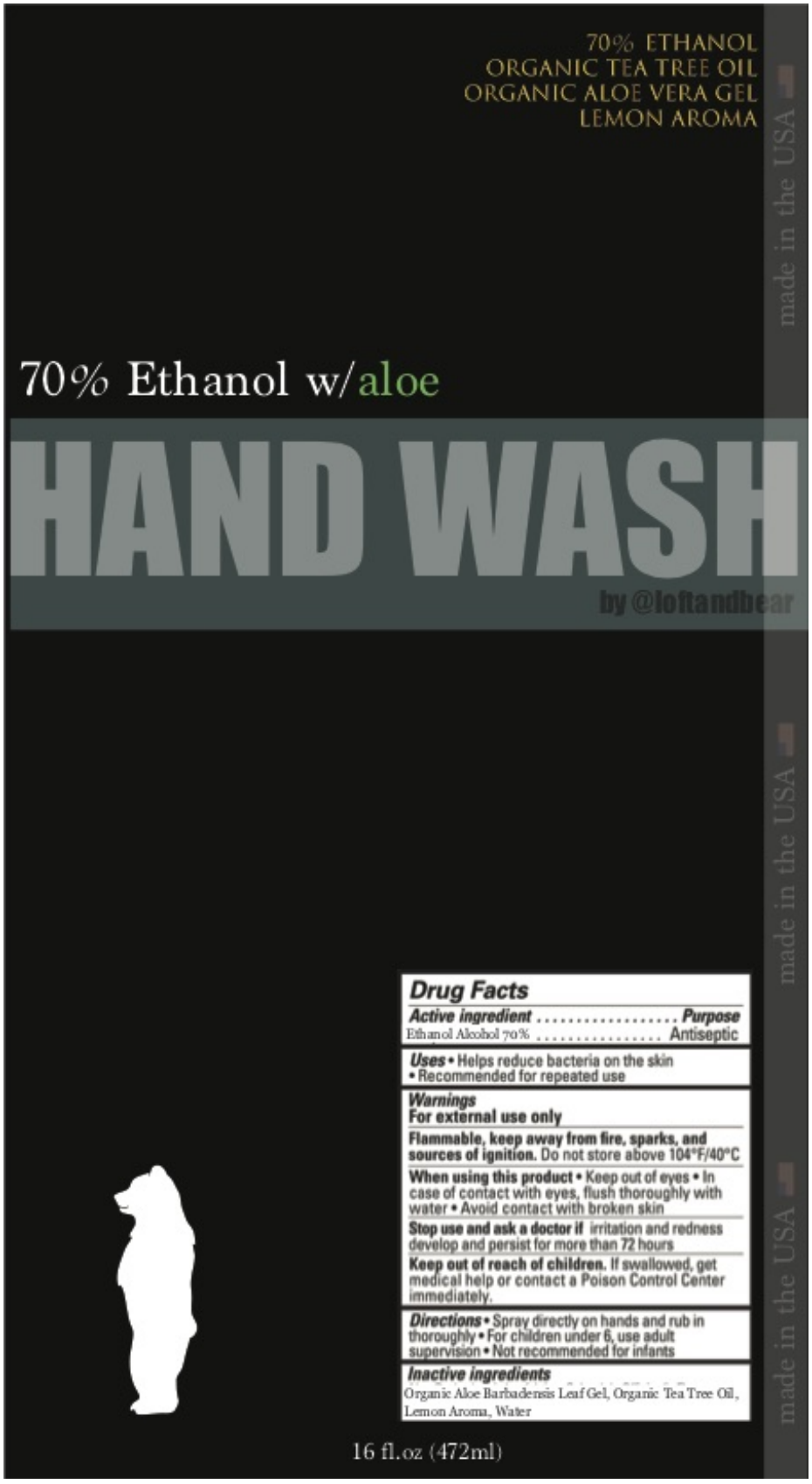
Inactive ingredients

Aloe Barbadensis Leaf liquid, Tea Tree Oil, purified water USP

Package Label - Principal Display Panel

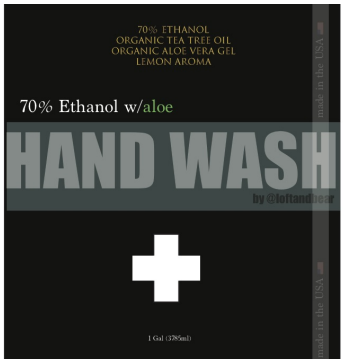


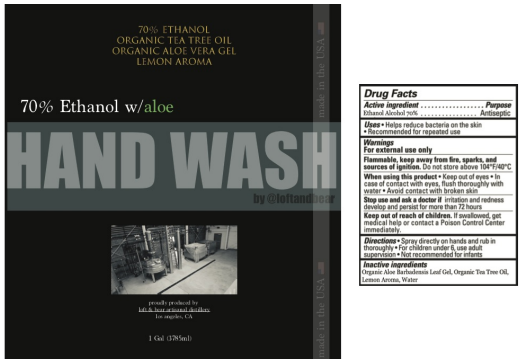
236 mL NDC: 77179-7008-1



473 mL NDC: 77179-7016-2

3785 mL NDC: 77179-7128-4





LOFT AND BEAR HAND WASH WITH ETHANOL ALCOHOL 16 OZ

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77179-7016
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	473 mL in 473 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	473 mL in 473 mL
TEA TREE OIL (UNII: VIF565UC2G)	473 mL in 473 mL
WATER (UNII: 059QF0KO0R)	473 mL in 473 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:77179-7016-2	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/12/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/12/2020	

LOFT AND BEAR HAND WASH WITH ETHANOL ALCOHOL 128 OZ/ 1 GALLON

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77179-7128
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	3785 mL in 3785 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	3785 mL in 3785 mL
TEA TREE OIL (UNII: VIF565UC2G)	3785 mL in 3785 mL
WATER (UNII: 059QF0KO0R)	3785 mL in 3785 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:77179-7128-4	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/12/2020	

LOFT AND BEAR HAND WASH WITH ETHANOL ALCOHOL 8 OZ

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77179-7008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	236 mL in 236 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	236 mL in 236 mL
TEA TREE OIL (UNII: VIF565UC2G)	236 mL in 236 mL

WATER (UNII: 059QF0KO0R)	236 mL in 236 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77179-7008-1	236 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/12/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/12/2020	

Labeler - Y. SA, INC (080269381)

Establishment

Name	Address	ID/FEI	Business Operations
Y. SA, INC		080269381	manufacture(77179-7008, 77179-7016, 77179-7128)

Revised: 5/2020 Y. SA, INC