

SIMPLY PURE HAND SANITIZER- alcohol gel

KKJ & Associates 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.

Simply Pure Hand Sanitizer

Active Ingredient(s)

Alcohol 70% v/v.

Purpose

Antiseptic

Use

This product is intended to help reduce bacteria on skin.

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.

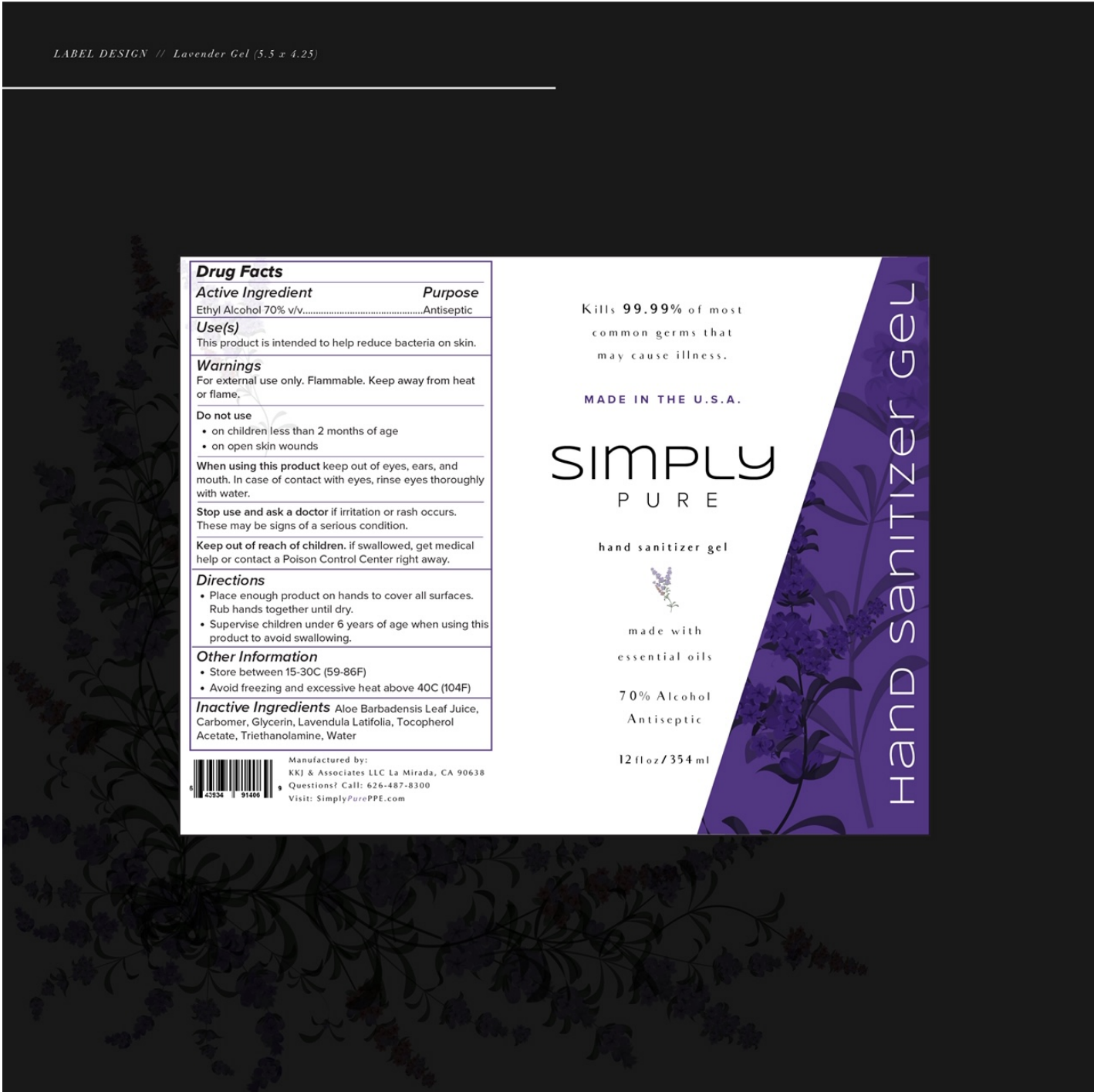
Other information

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

Inactive ingredients

Aloe Barbadensis Leaf Juice, Carbomer, Glycerin, Lavendula Latifolia, Tocopherol Acetate, Triethanolamine, water

Package Label - Principal Display Panel



SIMPLY PURE HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79642-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	70 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
TROLAMINE (UNII: 9O3K93S3TK)				
LAVENDER OIL (UNII: ZBP1YXW0H8)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79642-001-01	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:79642-001-02	296 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
3	NDC:79642-001-03	355 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
4	NDC:79642-001-04	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
5	NDC:79642-001-05	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
6	NDC:79642-001-06	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	03/30/2020	

Labeler - KKJ & Associates LLC (057060784)

Establishment

Name	Address	ID/FEI	Business Operations
KKJ & Associates LLC		057060784	manufacture(79642-001)