VARIGARD HAND SANITIZER- alcohol gel
VARIGARD, 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.

Active Ingredient

Ethyl Alcohol 62% v/v.

Purpose

Antiseptic

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 appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222

Directions

- Place enough product on hands to cover all surfaces.
- Supervise children under 6 years of age when using this product to avoid swallowing.

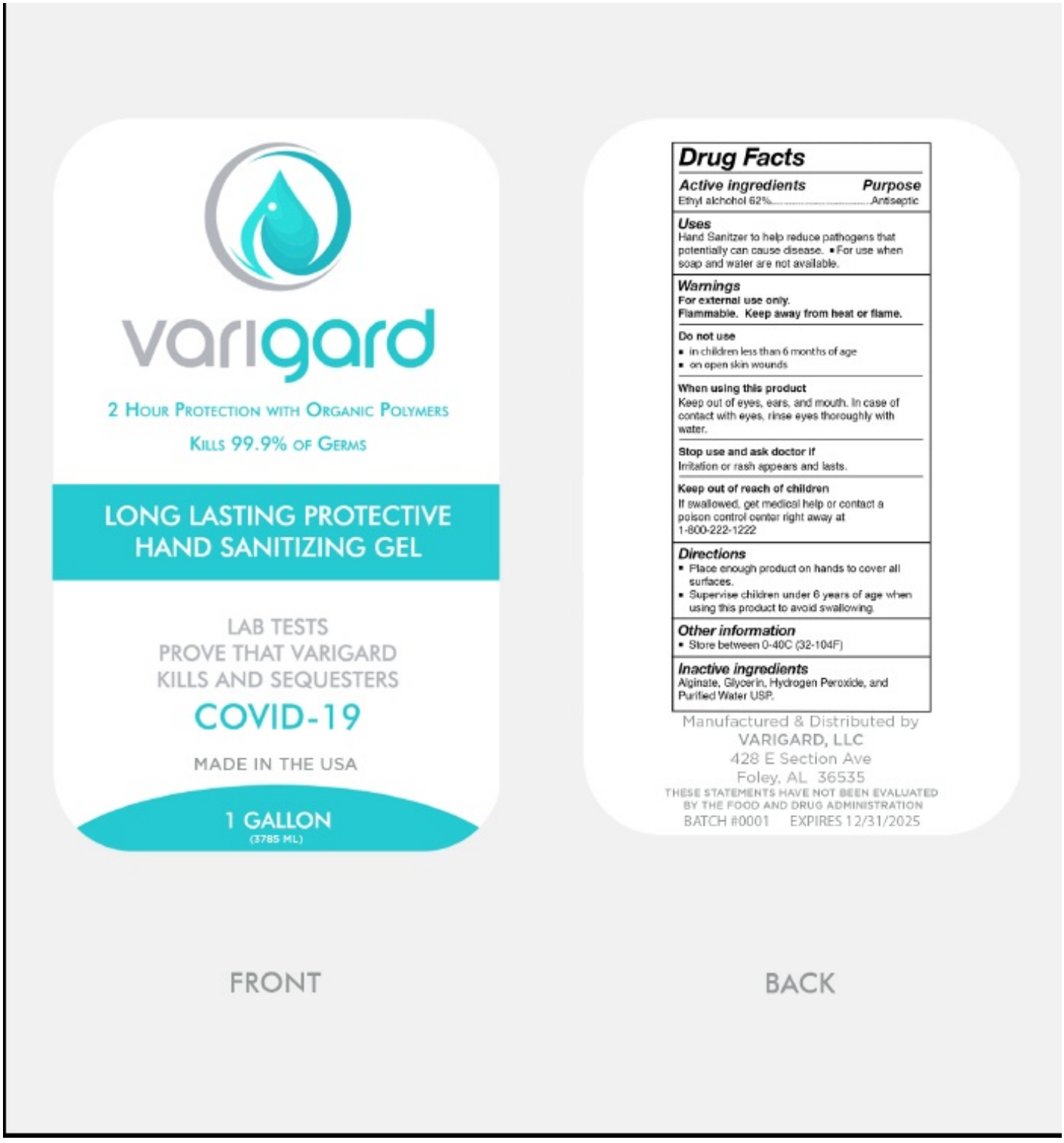
Other information

- Store between 0-40ºC (32-104ºF)

Inactive ingredients

Alginate, Glycerin, Hydrogen Peroxide, Purified Water USP

Product label



VARIGARD HAND SANITIZER alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80787-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80787-001-01	59 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/01/2020	
2	NDC:80787-001-02	118 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/01/2020	
3	NDC:80787-001-03	236 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/01/2020	
4	NDC:80787-001-04	946 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/01/2020	
5	NDC:80787-001-05	3785 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/01/2020	
6	NDC:80787-001-06	208175 mL in 1 DRUM; Type 0: Not a Combination Product	10/01/2020	
7	NDC:80787-001-07	1040875 mL in 1 DRUM; Type 0: Not a Combination Product	10/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/01/2020	

Labeler - VARIGARD, LLC (117676040)

Establishment

Name	Address	ID/FEI	Business Operations
VARIGARD, LLC		117676040	manufacture(80787-001)