HAND SANITIZER GEL 73% ALCOHOL ANTISEPTIC- alcohol gel
Solugen Blending 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.

Hand Sanitizer Gel 73% Alcohol Antiseptic

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This is a hand sanitizer manufactured according to the part333A of the OTC monograph.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage formulation)

a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (73%, volume/volume (v/v) in an aqueos solution denatured according to Alcohol and Tobacco Bureau regulations in 27 CFR part 20.

b. Glycerol (1.15% v/v).

c. Hydroxymethyl Cellulose (1.00% v/v).

d. Sterile distilled water or boiled cold water.

Active Ingredient(s)

Alcohol 73% 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

glycerin, methyl cellulose, purified water USP

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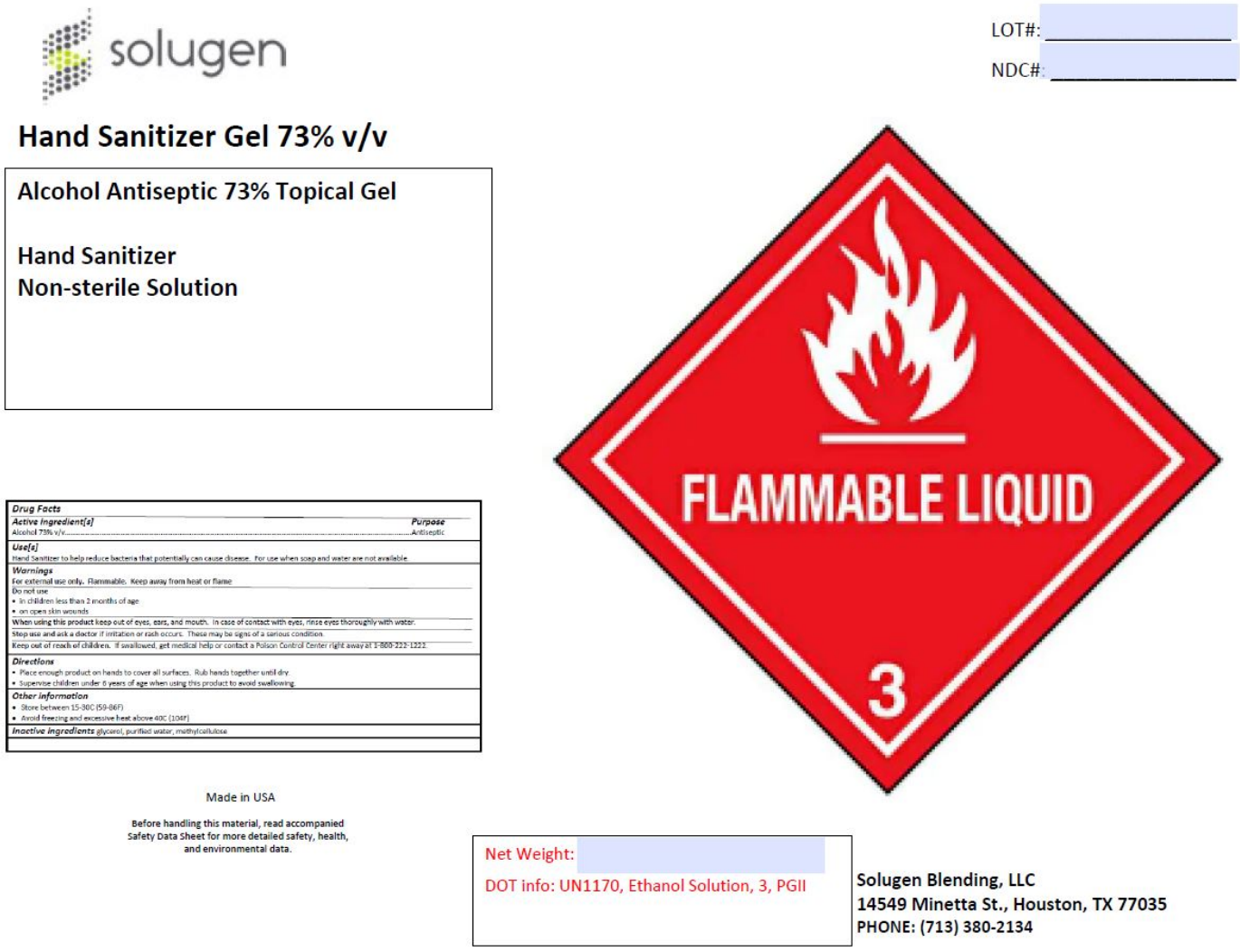

18927000 mL NDC: 79975-008-01

HAND SANITIZER GEL 73% ALCOHOL ANTISEPTIC alcohol gel	
Product Information	

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79975-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	73 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
HYDROXYMETHYL CELLULOSE (UNII: 273FM27VK1)	1 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.15 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79975-008-01	18927000 mL in 1 TANK; Type 0: Not a Combination Product	09/11/2020	
2	NDC:79975-008-02	1249000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	09/11/2020	
3	NDC:79975-008-03	208198 mL in 1 DRUM; Type 0: Not a Combination Product	09/11/2020	
4	NDC:79975-008-04	18927 mL in 1 DRUM; Type 0: Not a Combination Product	09/11/2020	
5	NDC:79975-008-05	3785 mL in 1 PAIL; Type 0: Not a Combination Product	09/11/2020	
6	NDC:79975-008-09	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/11/2020	

Labeler - Solugen Blending LLC (117590261)

Establishment

Name	Address	ID/FEI	Business Operations
Solugen Blending LLC		117590261	manufacture(79975-008)

Revised: 9/2020 Solugen Blending LLC