RESPONSIBLE HAND SANITIZER- alcohol liquid SanitizeNow 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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The hand sanitizer is manufactured using only the following ingredients in the preparation of the product:

Alcohol (ethanol) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.

Sterile distilled water or boiled cold water.

Hydrogen Peroxide

Glycerin

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% 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

Water, Hydrogen Peroxide, Glycerin.

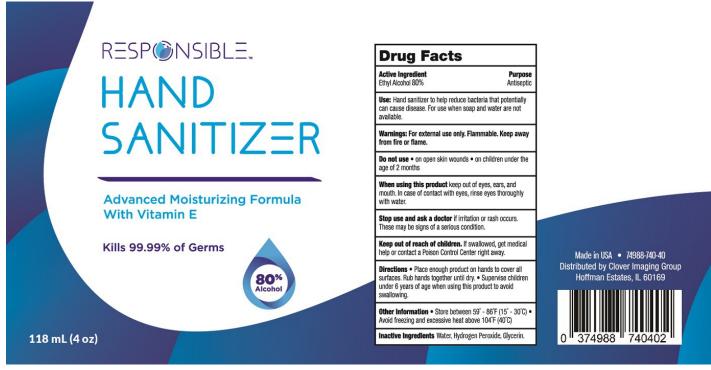
Package Label - Principal Display Panel

59 mL NDC: 74988-740-20





118 mL NDC: 74988-740-40

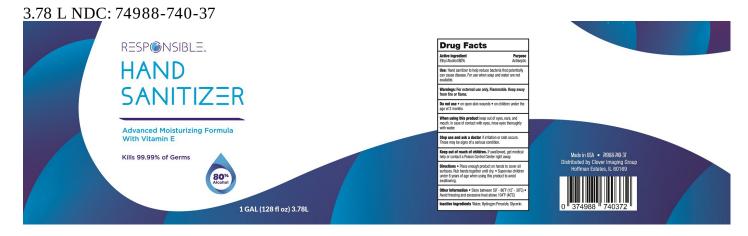


236 mL NDC: 74988-740-80



473 mL NDC: 74988-740-16





RESPONSIBLE HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74988-740
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:74988-740-20	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/05/2020		
2	NDC:74988-740-40	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/05/2020		
3	NDC:74988-740-80	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/05/2020		
4	NDC:74988-740-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/05/2020		
5	NDC:74988-740-37	3780 mL in 1 JUG; Type 0: Not a Combination Product	06/05/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	06/05/2020		

Labeler - SanitizeNow Inc. (117475870)

Registrant - SanitizeNow Inc. (117475870)

Establishment				
Name	Address	ID/FEI	Business Operations	
SanitizeNow Inc.		117475870	manufacture(74988-740)	

Revised: 1/2021 Sanitize Now Inc.