HAND SANITIZER- alcohol gel
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) (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.
Sterile distilled water or boiled cold water.
Hydrogen Peroxide
Glycerin
Isopropyl Misrate
Propylene Glycol
Carbomer and/or Crosspolymers
Aloe Arborescens Leaf
Tocopheryl Acetate
Fragrance

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 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
- in eyes. In case of contact, rinse eyes thoroughly with water

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, Carbomer and/or Crosspolymers, Isopropyl Myristate, Propylene Glycol, Aloe Arborescens Leaf, Tocopheryl Acetate, Fragrance.

Package Label - Principal Display Panel

59 mL NDC: 74988-736-20

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70%	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 fire or flame.

Do not use • on open skin wounds • on children under the age of 2 months

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

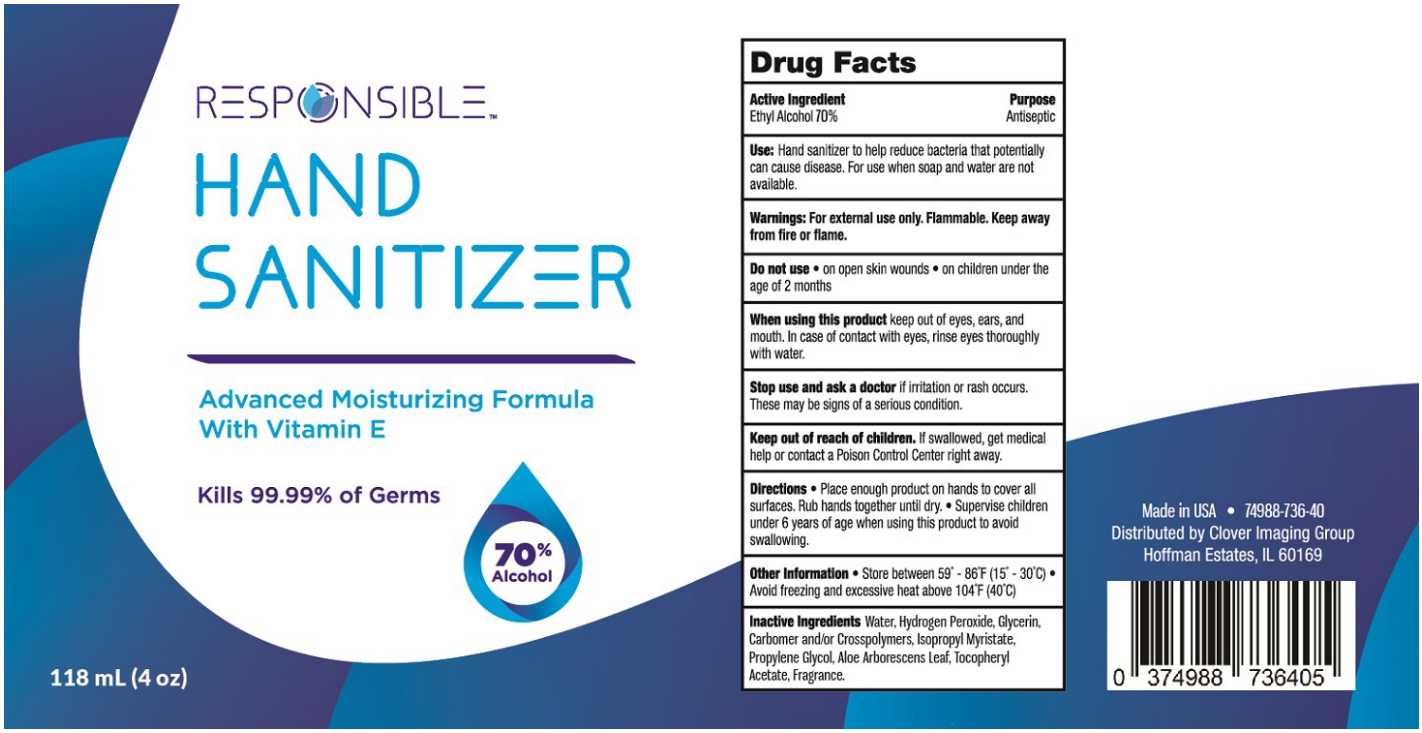
Inactive Ingredients Water, Hydrogen Peroxide, Glycerin, Carbomer and/or Crosspolymers, Isopropyl Myristate, Propylene Glycol, Aloe Arborescens Leaf, Tocopheryl Acetate, Fragrance.

PRO: 6/3/2020
EXP: 6/3/2022

Made in USA • 74988-736-20
Distributed by
Clover Imaging Group
Hoffman Estates, IL 60169

0 374988 736207

118 mL NDC: 74988-736-40



Drug Facts

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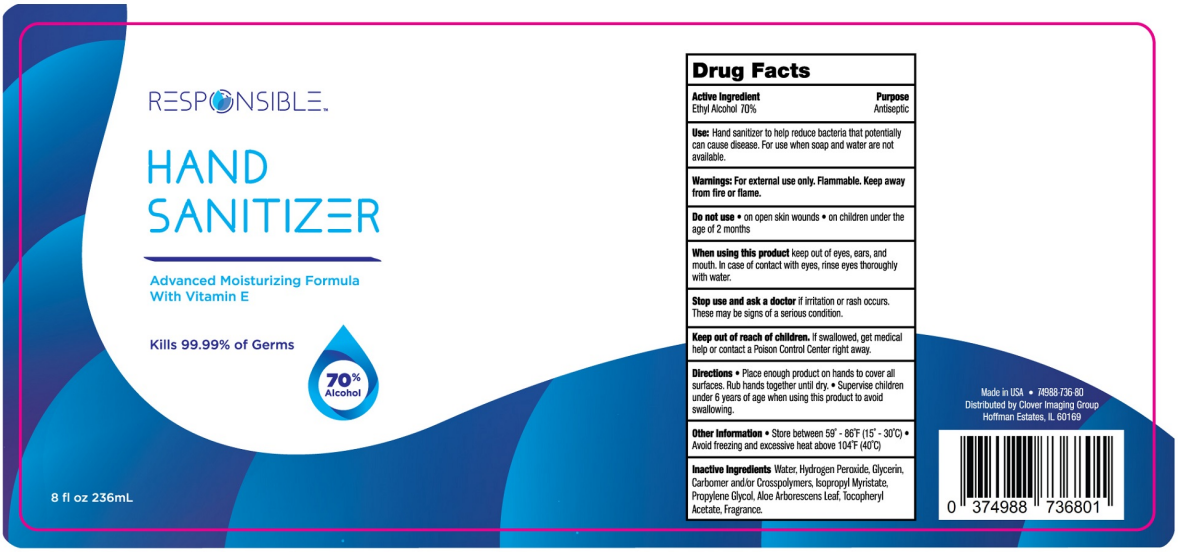
Made in USA • 74988-736-40
Distributed by Clover Imaging Group
Hoffman Estates, IL 60169

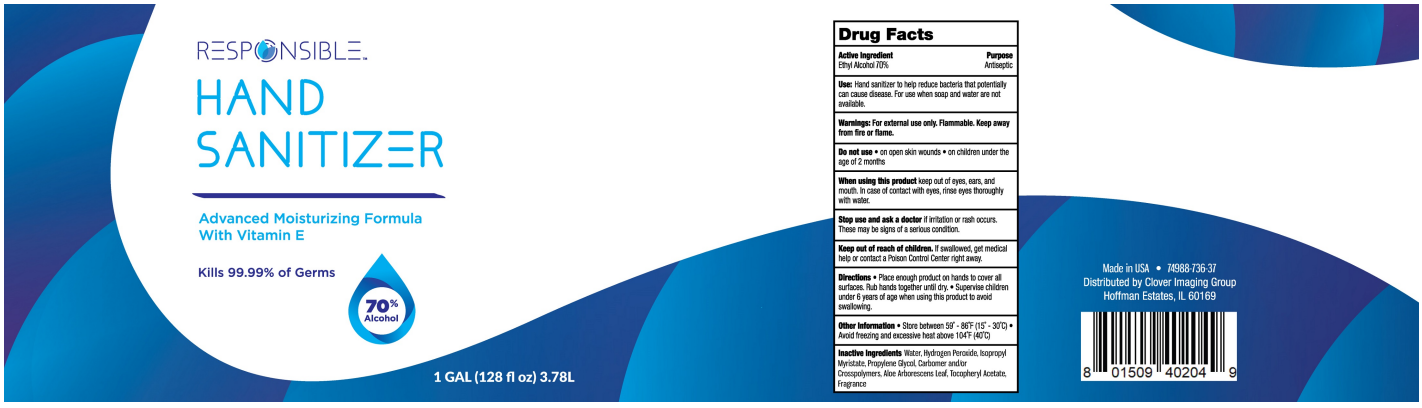
0 374988 736405

236 mL NDC: 74988-736-80



473 mL NDC: 74988-736-16

3.78 L NDC: 74988-736-37



HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:74988-736

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**
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE ARBORESCENS LEAF (UNII: 09TD8L5SQV)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74988-736-37	3800 mL in 1 JUG; Type 0: Not a Combination Product	06/05/2020	
2	NDC:74988-736-20	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/05/2020	
3	NDC:74988-736-40	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/05/2020	
4	NDC:74988-736-80	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/05/2020	
5	NDC:74988-736-16	473 mL in 1 BOTTLE; 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(74988-736)

Revised: 1/2021 SanitizeNow Inc.