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) (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
Carbomer 1342
Aloe Vera Leaf
FD&C Blue No. 1
FD&C Yellow No. 5
Alpha Tocopherol 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 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
- 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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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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 1342, Aloe Vera Leaf, FD&C Blue No. 1, FD&C Yellow No. 5, Alpha Tocopherol Acetate, Fragrance.

Package Label - Principal Display Panel

59 mL NDC: 74988-730-20

118 mL NDC: 74988-730-40

DRUG FACTS

Active Ingredient	Purpose
Alcohol 80%	Antiseptic

Use[s]
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
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Inactive ingredients Water, Hydrogen Peroxide, Glycerin, Carbomer 1342, Aloe Vera Leaf, FD&C Blue No. 1, FD&C Yellow No. 5, Alpha Tocopherol Acetate, Fragrance.

Shield your hands from germs and infections. Manufactured and bottle in the USA. FDA registered

FDA

0 374888 730403

Hand Sanitizer

Porrexx

High Potency Hand Sanitizer

HIGH POTENCY FORMULA • HIGH POTENCY FORMULA •
80% Alcohol Formula

Made with Plant Extracts and Skin Conditioner

KILLS 99.99% OF GERMS*

4 oz (118 mL)

01 Dispense hand sanitizer on your palms.

02 Rub hands together, palm to palm and back of each hand.

03 Rub tips of hand with palm of other hand.

04 Cover all surfaces until hands feel dry (about 20 sec.)

This product is FDA Registered
NDC: 74988-730-40

236 mL NDC: 74988-730-80

DRUG FACTS

Active Ingredient	Purpose
Alcohol 80%	Antiseptic

Use[s]
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.

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 1342, Aloe Vera Leaf, FD&C Blue No. 1, FD&C Yellow No. 5, Alpha Tocopherol Acetate, Fragrance.

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FDA

0 374988 730809

Hand Sanitizer

Porrexx

High Potency Hand Sanitizer

HIGH POTENCY FORMULA • HIGH POTENCY FORMULA •
80% Alcohol Formula

Made with Plant Extracts and Skin Conditioner

KILLS 99.99% OF GERMS*

8 oz (236 mL)

01 Dispense hand sanitizer on your palms.

02 Rub hands together, palm to palm and back of each hand.

03 Rub tips of hand with palm of other hand.

04 Cover all surfaces until hands feel dry (about 20 sec.)

This product is FDA Registered
NDC: 74988-730-80

473 mL NDC: 74988-730-16

DRUG FACTS

Active Ingredient — **Purpose**
Alcohol 80% — Antiseptic

Use[s]
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.

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 1342, Aloe Vera Leaf, FD&C Blue No. 1, FD&C Yellow No. 5, Alpha Tocopherol Acetate, Fragrance.

Shield your hands from germs and infections. Manufactured and bottle in the USA. FDA registered

FDA

0 374988 730168

Hand Sanitizer

Porrexx

High Potency Hand Sanitizer

HIGH POTENCY FORMULA • HIGH POTENCY FORMULA •
80% Alcohol Formula

Made with Plant Extracts and Skin Conditioner

KILLS 99.99% OF GERMS*

473 mL (16 oz)

01 Dispense hand sanitizer on your palms.

02 Rub hands together, palm to palm and back of each hand.

03 Rub tips of hand with palm of other hand.

04 Cover all surfaces until hands feel dry (about 20 sec.)

This product is FDA Registered
NDC: 74988-730-16

3.79 L NDC: 74988-730-37

DRUG FACTS

Active Ingredient(s) — **Purpose**
Alcohol 80% — Antiseptic

Use[s]
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 conditions.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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 (58-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients Water, Hydrogen Peroxide, Glycerin, Carbomer 1342, Aloe Vera Leaf, FD&C Blue No. 1, FD&C Yellow No. 5, Alpha Tocopherol Acetate, Fragrance.

Shield your hands from germs and infections. Manufactured and bottle in the USA. FDA registered

FDA

0 374988 730373

Hand Sanitizer

Porrexx

High Potency Hand Sanitizer

Made with Plant Extracts and Skin Conditioner

KILLS 99.99% OF GERMS*

HIGH POTENCY FORMULA • HIGH POTENCY FORMULA •
80% Alcohol Formula

3.79L (1 Gal)

01 Dispense hand sanitizer on your palms.

02 Rub hands together, palm to palm and back of each hand.

03 Rub tips of hand with palm of other hand.

04 Cover all surfaces until hands feel dry (about 20 sec.)

This product is FDA Registered
NDC: 74988-730-37

208 L NDC: 74988-730-55

1041 L NDC: 74988-730-41

25741 L NDC: 74988-730-74

HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:74988-730
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**
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
CARBOMER 1342 (UNII: 809Y72KV36)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74988-730-20	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020	
2	NDC:74988-730-80	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020	
3	NDC:74988-730-40	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020	
4	NDC:74988-730-37	3790 mL in 1 JUG; Type 0: Not a Combination Product	05/20/2020	
5	NDC:74988-730-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020	
6	NDC:74988-730-55	208000 mL in 1 DRUM; Type 0: Not a Combination Product	05/20/2020	
7	NDC:74988-730-41	1041000 mL in 1 TANK; Type 0: Not a Combination Product	05/20/2020	
8	NDC:74988-730-74	25741000 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - SanitizeNow Inc. (117475870)

Establishment

Name	Address	ID/FEI	Business Operations
SanitizeNow Inc.		117475870	manufacture(74988-730)