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) 75%, 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

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 75% 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 and/or Crosspolymers, Isopropyl Myristate, Aloe Arborescens Leaf, Tocopheryl Acetate, Fragrance.

Package Label - Principal Display Panel

59 mL NDC: 74988-732-20 **Hand Sanitizer Drug Facts** Shield your hands from Narnings: For external use only. Flammable. Keep away rom fire or flame. germs and infections. Do not use • on open skin wounds • on children under the Manufactured and **High Potency Hand Sanitizer** When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly bottle in the USA. FDA Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition registered Keep out of reach of children. If swallowed, get medical **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 Made with Plant Extracts and Rub tips of hand with palm Skin Conditioner Other Information • Store between 59° - 86°F (15° - 30°C) •
Avoid freezing and excessive heat above 104°F (40°C) hands feel dry (about 20 KILLS 99.99% OF GERMS Inactive Ingredients Water, Hydrogen Peroxide, Glycerin, Carbomer and/or Crosspolymers, Isopropyl Myristate, Aloe Arborescens Leaf, Tocopheryl Acetate, Fragrance. This product is FDA Registered NDC: 74988-732-20 59 mL (2 oz)

118 mL NDC: 74988-732-40

Drug Facts

Use: Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not

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

Hand Sanitizer

Shield your hands from germs and infections. Manufactured and





Made with Plant Extracts and Skin Conditioner

KILLS 99.99% OF GERMS*







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





Rub tips of hand with palm



hands feel dry (about 20

This product is FDA Registered NDC: 74988-732-40

118 mL (4 oz)

Drug Facts

236 mL NDC: 74988-732-80

Active Ingredient Ethyl Alcohol 75%

Purpose

bottle in the

USA. FDA registered

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

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly

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 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, Aloe Arborescens Leaf, Tocopheryl Acetate, Fragrance.









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

Hand Sanitizer



High Potency Hand Sanitizer



Made with Plant Extracts and Skin Conditioner

KILLS 99.99% OF GERMS*





This product is FDA Registered NDC: 74988-732-80

236 mL (8 oz)

473 mL NDC: 74988-732-16

Drug Facts 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 When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly **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

Other Information • Store between 59° - 86°F (15° - 30°C) • Avoid freezing and excessive heat above 104°F (40°C)

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Hand Sanitizer

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



High Potency Hand Sanitizer



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KILLS 99.99% OF GERMS*









Rub tips of hand with pa of other hand.



Cover all surfaces until hands feel dry (about 20

473 mL (16 oz)

This product is FDA Registered NDC: 74988-732-16

3.79 L NDC: 74988-732-37

Drug Facts When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly 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 childre under 6 years of age when using this product to avoid

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









High Potency Hand Sanitizer



Made with Plant Extracts and Skin Conditioner KILLS 99.99% OF GERMS









This product is FDA Registere
NDC: 74988-732-37

208 L NDC: 74988-732-55

Drug Facts

Ethyl Alcohol 75%

Purpose Antiseptio

Use: Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not

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

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly

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 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, Aloe Arborescens Leaf, Tocopheryl Acetate, Fragrance.

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













Hand Sanitizer



High Potency Hand Sanitizer



Made with Plant Extracts and Skin Conditioner

KILLS 99.99% OF GERMS*

208 L (55 Gal)

This product is FDA Registered NDC: 74988-732-55

1041 L NDC: 74988-732-41

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







Made with Plant Extracts and Skin Conditioner

Hand Sanitizer









This product is EDA Regist NDC: 74988-732-41

25741 L NDC: 74988-732-74

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





















This product is FDA Registered NDC: 74988-732-74

HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG

Route of Administration

TOPICAL

Item Code (Source)

NDC:74988-732

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL		

Inactive Ingredients				
Ingredient Name	Strength			
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)				
GLYCERIN (UNII: PDC6 A3C0 OX)				
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)				
WATER (UNII: 059QF0KO0R)				
CARBOMER HO MO PO LYMER, UNSPECIFIED TYPE (UNII: 0 A5MM30 7FC)				
ALOE ARBORESCENS LEAF (UNII: 09TD8L5SQV)				
.ALPHATO COPHEROL ACETATE, D- (UNII: A7E6112E4N)				

Packaging				
#	Item Code Package Description		Marketing Start Date	Marketing End Date
1	NDC:74988-732- 20	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2020	
2	NDC:74988-732- 40	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2020	
3	NDC:74988-732- 80	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2020	
4	NDC:74988-732- 16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2020	
5	NDC:74988-732- 37	3790 mL in 1 JUG; Type 0: Not a Combination Product	06/15/2020	
6	NDC:74988-732- 55	208000 mL in 1 DRUM; Type 0: Not a Combination Product	06/15/2020	
7	NDC:74988-732- 41	1041000 mL in 1 TANK; Type 0: Not a Combination Product	06/15/2020	
8	NDC:74988-732- 74	25741000 mL in 1 CONTAINER; Type 0: Not a Combination Product	06/15/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Monograph Citation Marketing Start Date		
OTC monograph not final	part333A	06/15/2020		

Labeler - SanitizeNow Inc. (117475870)

Establishment				
Name	Address	ID/FEI	Business Operations	
SanitizeNow Inc.		117475870	manufacture(74988-732)	

Revised: 6/2020 Sanitize Now Inc.