HAND SANITIZER- alcohol-free 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:

Benzalkonium Chloride 0.26%

Propylene Glycol

Cocamidolpropyl PG-Dimonium Chloride Phospate

Sterile distilled water or boiled cold water.

Triethylene Glycol

Polysorbate 20

FD&C Blue No. 1

FD&C Yellow No. 5

Xanthan Gum

Aloe Vera Leaf

Lemon

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)

Benzalkonium chloride 0.26% 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.

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 below 43C Avoid extreme temperatures above 100C (212F)

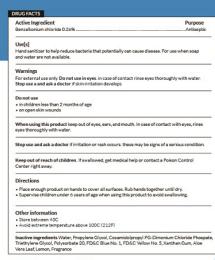
Inactive ingredients

Water, Propylene Glycol, Cocamidolpropyl PG-Dimonium Chloride Phospate, Triethylene Glycol, Polysorbate 20, FD&C Blue No. 1, FD&C Yellow No. 5, Xanthan Gum, Aloe Vera Leaf, Lemon, Fragrance

Package Label - Principal Display Panel

59 mL NDC: 74988-114-20 DRUG FACTS Hand Sanitizer For external use only. **Do not use in eyes** in case of contact rinse eyes thoroughly with water **Stop use and ask a doctor** if akin irritation develops o not use in children less than 2 months of age Rub hands together, palm to palm and back of each hand. **High Potency Hand Sanitizer** Dispense hand sanitizer on 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 Store between 43C
 Avoid extreme temperatures above 100C (212F) Made with Plant Extracts and Inactive ingredients Water, Propylene Glycol, Cocamidolpropyl PG-Dimonium Chloride Phospate, Triethylene Glycol, Polysorbate 20, FDSC Blue No. 1, FDSC Yellow No. 5, Xanthan Gum, Aloe Vera Leaf, Lemon, Fragrance Skin Conditioner KILLS 99.99% OF GERMS* Shield your hands from germs and infections. Manufactured and bottle in the USA. FDA registered This product is FDA Registered NDC: 74988-114-20 59 mL (2 oz)

118 mL NDC: 74988-114-40



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*

4 oz (118 mL)



Dispense hand sanitizer on your palms.



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



Rub tips of hand with palm of other hand.



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

This product is FDA Registered NDC: 74988-114-40

236 mL NDC: 74988-114-80



473 mL NDC: 74988-114-16



473 mL (16 oz)



208 L NDC: 74988-114-55

DRUG FACTS Active Ingredient Purpose Benzalkonium chloride 0.26%. Antiseptic 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 casea 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. 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. Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) Inactive ingredients Water, Propylene Glycol, Cocamidolpropyl PG-Dimonium Chloride Phospate, Triethylene Glycol, Polysorbate 20, FD&C Blue No. 1, FD&C Yellow No. 5, Xanthan Gum, Aloe Vera Leaf, Lemon, Fragrance Shield your hands from germs and infections.

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: 74988-114-55

1041 L NDC: 74988-114-41



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





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

1041 L (275 Gal)

Hand Sanitizer









This product is FDA Registered NDC: 74988-114-41

25741 L NDC: 74988-114-74



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













This product is FDA Registered NDC: 74988-114-74

HAND SANITIZER

alcohol-free gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:74988-114

Route of Administration

TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
COCAMIDO PRO PYL PG-DIMO NIUM CHLO RIDE PHO SPHATE (UNII: H2KVQ 74JM4)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
TRIETHYLENE GLYCOL (UNII: 3P5SU53360)		
POLYSORBATE 20 (UNII: 7T1F30V5YH)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		
XANTHAN GUM (UNII: TTV12P4NEE)		
LEMON (UNII: 24RS0A988O)		
WATER (UNII: 059QF0KO0R)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:74988-114- 20	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020		
2	NDC:74988-114- 80	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020		
3	NDC:74988-114- 40	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020		
4	NDC:74988-114- 37	3790 mL in 1 JUG; Type 0: Not a Combination Product	05/20/2020		
5	NDC:74988-114- 16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020		
6	NDC:74988-114- 55	208000 mL in 1 DRUM; Type 0: Not a Combination Product	05/20/2020		
7	NDC:74988-114- 41	1041000 mL in 1 TANK; Type 0: Not a Combination Product	05/20/2020		
8	NDC:74988-114- 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	05/20/2020			

Labeler - SanitizeNow Inc. (117475870)

Establishment			
Name	Address	ID/FEI	Business Operations
SanitizeNow Inc.		117475870	manufacture (74988-114)

Revised: 6/2020 Sanitize Now Inc.