

HAND SANITIZER- alcohol-free 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.

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.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product:

- a. Benzalkonium chloride 0.26%
- b. Propylene glycol
- c. Cocamidolpropyl PG-Dimonium Chloride Phosphate
- d. Sterile distilled water or boiled cold water.
- e. Triethylene glycol
- f. Polysorbate 20
- g. Fragrance
- h. FD&C Blue No. 1

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.

Stop use and ask a doctor if irritation or rash occurs.

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, Cocamidolpropyl PG-Dimonium Chloride Phospate, Propylene glycol, Triethylene glycol, Polysorbate 20, Fragrance, FD&C Blue No. 1

Package Label - Principal Display Panel

3790 mL NDC: 74988-112-37

Hand Sanitizer
 Alcohol-Free Antiseptic
 Topical Solution

Hand Sanitizer
 Non-sterile Solution

3.79 L (3790 mL)

NDC: 74988-112-37

Drug Facts	
Active ingredient	Purpose
Benzalkonium chloride 0.26%.....	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. Do not use in eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if skin irritation develops	
Do not use	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Store below 43C • Avoid extreme temperatures above 100C (212F) 	
Inactive ingredients Water, Cocamidopropyl PG-Dimonium Chloride Phosphate, Propylene glycol, Triethylene glycol, Polysorbate 20, Fragrance, FD&C Blue No. 1	



alcohol-free liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74988-112
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
COCAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: H2KVQ74JM4)	
TRIETHYLENE GLYCOL (UNII: 3P5SU53360)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74988-112-37	3790 mL in 1 JUG; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/01/2020	

Labeler - SanitizeNow Inc. (117475870)

Establishment

Name	Address	ID/FEI	Business Operations
SanitizeNow Inc.		117475870	manufacture(74988-112)

Revised: 4/2020

SanitizeNow Inc.