

REEARTH HAND SANITIZER WIPE- benzalkonium chloride cloth
NuGenTec

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.

re:earth wipe Hand Sanitizer

Active Ingredient(s)

Benzalkonium Chloride 0.13%

Purpose

Antiseptic, Hand Sanitizer, Antibacterial

Use

Hand Sanitizer wipe 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.

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Directions

- Wet hands thoroughly with the product to cover all surfaces. Allow to dry without wiping.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 0-40C (32-104F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

200 in Canister NDC: 77368-011-20

ACTIVE INGREDIENTS: Benzalkonium chloride 0.12 wt%
Hydrogen peroxide 0.12 wt%

Helps prevent the risk of skin infection

This product kills *Staphylococcus aureus*, *Salmonella enterica*, *Pseudomonas aeruginosa*, *Campylobacter jejuni*,
Influenza Type A virus, *Escherichia coli* (E. coli) and SARS-CoVid-19 (Coronavirus)

Kills 99.99% of Germs

re:earth™

Antiseptic Benzalkonium Chloride Towelette

NET CONTENTS:
400 Wipes
5 lbs. 10 oz. (2560 g)* • 1200 ml
*includes weight of plastic canister

BLEACH FREE
KEEP OUT OF REACH OF CHILDREN
CAUTION
SEE LABEL FOR PRECAUTIONARY STATEMENTS AND FIRST AID

Healthy people.
Healthy planet.

EARTH FOR ONE REASON

Cleans and disinfects hands.

Use on and household surfaces:

- Tubs and shower stalls
- Telephone
- Doorknobs
- Stovetop and kitchen counters
- Faucets and sinks
- Exterior toilet surfaces

Gentle, soap-drying

Keeps Odor Fresh Sooner

Prevents the Spread of H2O2

DIRECTIONS FOR USE:
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

To Clean:
First and foremost to help prevent the risk of infection in home care, schools and homes.

To Clean and Disinfect:
Wipe hard, non-porous surfaces with moist wipe and surface is moist and thoroughly wet. Allow at least 30 seconds to allow wet surface to dry thoroughly. If surface is very dirty, use another wipe to clean and a third wipe to disinfect.
Do not use on leather, plastic, dyes, glassware and/or eating utensils.

PRECAUTIONARY STATEMENTS
HAZARDOUS TO HUMANS AND ANIMALS:
Causes eye irritation. Avoid contact with eyes.

First aid:
If in eyes, flush eye open and close slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after 15-20 minutes. Then continue flushing eye. Call a poison control center or doctor for treatment advice. Flush the product container or label with your other safety precaution labels or other or going to treatment facility.

STORAGE AND DISPOSAL:
Store in original container to avoid eye accidents in children. Keep securely closed. Non-refillable container. Do not reuse or refill this container. Recycle empty container in recycling if available.

Made for SAKI Inc.
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EPA REG. NO. 333-000-0000



REARTH HAND SANITIZER WIPE

benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77368-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	6.8 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.1 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77368-011-20	0.13 mL in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

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

Labeler - NuGenTec (090331927)

Registrant - NuGenTec (090331927)

Establishment

Name	Address	ID/FEI	Business Operations
NuGenTec		090331927	manufacture(77368-011)

Revised: 10/2020

NuGenTec