

REEARth HAND SANITIZER- benzalkonium chloride liquid
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%

hydrogen Peroxide.1%

Purpose

Antiseptic, Hand Sanitizer, Antibacterial

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. Avoid Contact with Eyes.

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, purified water USP, Aloe, Fragrance, Sodium Citrate, Phenoxyethanol, Polysorbate 20

Package Label - Principal Display Panel

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

Powered by All-Natural H₂O₂

re:earth™

BLEACH FREE

Hand Sanitizing Liquid

NET CONTENTS:
1 Gallon (128 oz)

Powered by All-Natural H₂O₂

Earth-Friendly, Germ-Deadly

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

To Clean and Disinfect:
Wet hands with re:earth Hand Sanitizer and rub hands together until dry. Allow to air dry. If surfaces are very dirty, re-wet hands to clean/disinfect.

Do Not Use to disinfect plates, dishes, glassware and/or eating utensils - Not Intended for food contact surfaces.

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

First aid:
If in EYES: Hold eye open and rinse slowly and gently with water for 10-20 minutes. Remove contact lenses, if present, after first five minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling poison control center or doctor or going to treatment facility.

STORAGE AND DISPOSAL:
Store in original container in areas inaccessible to children. Keep securely closed. Non-refillable container. Do not reuse or refill this container. Discard empty container in recycling (if available).
Discard wipe in trash. DO NOT FLUSH DOWN TOILET.

ACTIVE INGREDIENTS:
Benzalkonium chloride 0.13% w/v
Hydrogen peroxide 0.1% w/v
INACTIVE INGREDIENTS: Water, Aloe, Fragrance, Sodium Citrate, Phenoxyethanol, Glycerin, Polysorbate 20
FDA NDC: 77368-011-20

KEEP OUT OF REACH OF CHILDREN
CAUTION

Made for SANI Inc.
303 East 17th Avenue, Suite 920
Denver, CO 80203
Tel: 303.832.4355

1 Gallon in Bottle NDC: 77368-021-01

REARTH HAND SANITIZER

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77368-021
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.5 mL in 100 mL
SODIUM CITRATE (UNII: 1Q73Q2JULR)	0.05 mL in 100 mL
ALOE (UNII: V5VD430YW9)	0.1 mL in 100 mL
POLYSORBATE 20 (UNII: 7T1F30V5YH)	0.2 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.1 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77368-021-01	3786 mL in 1 CANISTER; Type 0: Not a Combination Product	10/13/2020	

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(77368-021)