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.

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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.

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

- 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

1 Gallon in Bottle NDC: 77368-021-01

REEARTH 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)

Revised: 10/2020 NuGenTec