**REEARTH HAND SANITIZER- benzalkonium chloride gel**
**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: 77368-022-01

| **REEARTH HAND SANITIZER** |
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| benzalkonium chloride gel |

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:77368-022 |
| **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:77368-022-01 | 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(77368-022) |

Revised: 10/2020 NuGenTec