**SANTI-GEL INSTANT HAND SANITIZER- santi-gel instant hand sanitizer solution**
**Kutol Products Company, 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.*

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**Santi-Gel Instant Hand Sanitizer**

**Flammable. Keep away from heat or flame.**

**For external use only.**

**Do not use** in the eyes. In case of contact, immediately flush with water.

**Stop use and ask a doctor if** irritation or rash appears and lasts.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Ethyl Alcohol 62% v/v.....Antibacterial Agent

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Water, Glycerin, Propylene Glycol, Isopropyl Mryistate, Aloe Barbadensis leaf, Tocopheryl Acetate (Vitamin E), Carbomer, Aminomethyl Propanol

To decrease bacteria on skin, apply a small amount to palm. Briskly rub, covering hands with product until dry.

Children under 6 years of age should be supervised when using this product.

Hand Sanitizer to help reduce bacteria on the skin that could cause disease. Recommended for repeated use.

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Do not use in the eyes. In case of contact, immediately flush with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.


50865-056-65.jpg

# SANTI-GEL INSTANT HAND SANITIZER

santi-gel instant hand sanitizer solution

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:50865-056 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ALCOHOL** (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 62.5 mL in 100 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **POLYACRYLIC ACID (250000 MW)** (UNII: 9G2MAD7J6W) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **ISOPROPYL MYRISTATE** (UNII: 0RE8K4LNJS) | |
| **AMINOMETHYLPROPANOL** (UNII: LU49E6626Q) | |

| | |
|---|---|
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| **.ALPHA.-TOCOPHEROL ACETATE, DL-** (UNII: WR1WPI7EW8) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:50865-056-12 | 1200 mL in 1 BAG; Type 0: Not a Combination Product | 05/22/2013 | 05/10/2017 |
| **2** | NDC:50865-056-19 | 236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/22/2013 | |
| **3** | NDC:50865-056-30 | 473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/22/2013 | |
| **4** | NDC:50865-056-34 | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/22/2013 | |
| **5** | NDC:50865-056-35 | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/22/2013 | |
| **6** | NDC:50865-056-65 | 800 mL in 1 BAG; Type 0: Not a Combination Product | 05/22/2013 | 05/10/2017 |
| **7** | NDC:50865-056-79 | 1892 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 05/22/2013 | |
| **8** | NDC:50865-056-82 | 800 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/22/2013 | 07/17/2016 |
| **9** | NDC:50865-056-86 | 800 mL in 1 BAG; Type 0: Not a Combination Product | 05/22/2013 | 07/19/2016 |
| **10** | NDC:50865-056-93 | 1200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/22/2013 | 05/10/2017 |
| **11** | NDC:50865-056-36 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/22/2013 | |
| **12** | NDC:50865-056-66 | 800 mL in 1 BAG; Type 0: Not a Combination Product | 05/10/2017 | |
| **13** | NDC:50865-056-03 | 208175 mL in 1 DRUM; Type 0: Not a Combination Product | 05/15/2015 | |
| **14** | NDC:50865-056-38 | 800 mL in 1 BAG; Type 0: Not a Combination Product | 05/10/2017 | |
| **15** | NDC:50865-056-43 | 236 mL in 1 BOTTLE; Type 0: Not a Combination Product | 01/01/2020 | |
| **16** | NDC:50865-056-07 | 3875 mL in 1 BOTTLE; Type 0: Not a Combination Product | 01/01/2019 | |
| **17** | NDC:50865-056-67 | 2000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 01/01/2019 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part333A | 05/22/2013 | |

## Labeler - Kutol Products Company, Inc. (004236139)

## Registrant - Kutol Products Company, Inc. (004236139)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Kutol Products Company | | 004236139 | manufacture(50865-056) |

Revised: 8/2023

Kutol Products Company, Inc.