**ADVANCED ALCOHOL GEL SANITIZER- alcohol gel**
**Betco Corporation, Ltd**

*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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**Advanced Alcohol Gel Sanitizer**

## Active Ingredient

Active Ingredient

Ethyl Alcohol 70%

## Uses

Uses

• Hand sanitizer to reduce microorganisms on the skin.

• Use this product when soap and water are not available.

## Purpose

Purpose

Antiseptic

## Warnings

Warnings

• For external use only.

• Avoid contact with eyes. If contact occurs, rinse thoroughly with water.

• FLAMMABLE. This product contains ethyl alcohol. Keep away from

sources of ignition.

• Discontinue use if irritation or redness develops.

• If irritation persists for more than 72 hours, consult a physician.

• KEEP OUT OF REACH OF CHILDREN.

• If swallowed, get medical help or contact a Poison Control Center right away.

## Directions

Directions

- Read the entire label before using this product.
- Place enough product on your palm to thoroughly cover your hands.
- Rub hands together briskly until dry.

## Inactive Ingredients

Inactive Ingredients

Water, PEG/PPG-8/3 Laurate, Gycerin, Carbomer, Tetrahydroxypropylethylendiamine, Fragrance.

## Warnings

KEEP OUT OF REACH OF CHILDREN.

## Principal Display Panel


# ADVANCED ALCOHOL GEL SANITIZER

alcohol gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:65601-801 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ALCOHOL** (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 0.7 mL in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |
| **CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)** (UNII: 59TL3WG5CO) | |
| **DIMETHICONE PEG-8 LAURATE** (UNII: 72MF9C2A18) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |

| | |
|---|---|
| **EDETOL** (UNII: Q4R969U9FR) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:65601-801-19 | 900 mL in 1 BAG; Type 1: Convenience Kit of Co-Package | 08/01/2019 | |
| **2** | NDC:65601-801-29 | 1000 mL in 1 BAG; Type 0: Not a Combination Product | 08/01/2019 | |
| **3** | NDC:65601-801-57 | 550 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 08/01/2019 | |
| **4** | NDC:65601-801-04 | 3780 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/01/2019 | |
| **5** | NDC:65601-801-55 | 208198 mL in 1 DRUM; Type 0: Not a Combination Product | 08/01/2019 | |
| **6** | NDC:65601-801-99 | 1041000 mL in 1 CONTAINER; Type 0: Not a Combination Product | 07/01/2021 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part333E | 08/01/2019 | |

## Labeler - Betco Corporation, Ltd (024492831)

## Registrant - Betco Corporation, Ltd (024492831)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Betco Corporation, Ltd | | 024492831 | manufacture(65601-801) , label(65601-801) |

Revised: 6/2022 Betco Corporation, Ltd