MINIONS HAND SANITIZER GEL- alcohol gel Ester Co., 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.

[Ester Co., Ltd.-MINIONS HAND SANITIZER GEL] 500 ml: BOTTLE+PUMP: 74004-701-01



MINIONS HAND SANITIZER GEL

alcohol gel

| Product Information | | | | |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:74004-701 | |
| Route of Administration | TOPICAL | | | |

| Active Ingredient/Active Moiety | | | |
|--|-------------------|------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 350 mL in 500 mL | |

| Inactive Ingredients | | | |
|--|----------|--|--|
| Ingredient Name | Strength | | |
| ALLANTO IN (UNII: 344S277G0Z) | | | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | | | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | | | |
| EDETOL (UNII: Q4R969U9FR) | | | |
| CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC) | | | |
| WATER (UNII: 059QF0KO0R) | | | |

ALOE ARBORESCENS LEAF (UNII: 09TD8L5SQV)

GLYCERIN (UNII: PDC6A3C0OX)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|----------------------|---|-------------------------|-----------------------|
| 1 | NDC:74004-701- 01 | 500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 05/21/2020 | |

Marketing Information

| 9 | | | |
|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333A | 05/21/2020 | |
| 4 | | | |

Labeler - Ester Co., Ltd. (688425766)

| Establishment | | | | |
|-----------------|---------|-----------|-------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Ester Co., Ltd. | | 688425766 | manufacture (74004-701) | |

Revised: 5/2020 Ester Co., Ltd.