HAND SANITIZER- alcohol gel Landy International

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.

51706-902 hand sanitizer 62% alcohol advanced formula

Active Ingredient(s)

Ethyl Alcohol 62%

Purpose

Antiseptic

Use

- ■decreases bacteria on the skin that could cause disease
- ■recommended for repeated use

Warnings

For external use only: hands

Flammable, keep away from fire or flame.

When using this product

■keep out of eyes. In case of contact with eyes flush thoroughly with water.

avoid contact with broken skin

■do not inhale or ingest

Stop use and ask doctor if

■irritation and redness develop

n condition persists for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

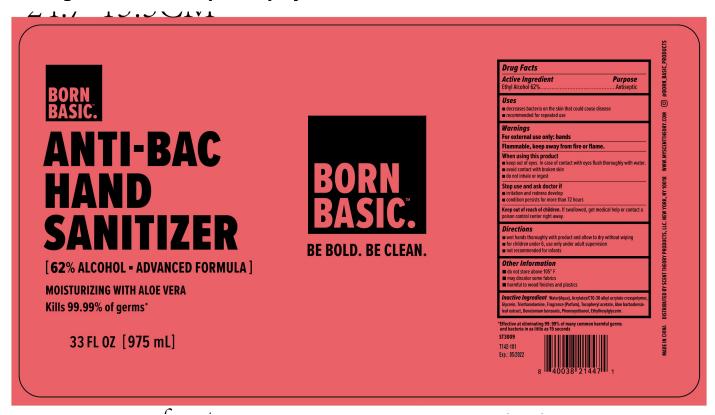
wet hands thoroughly with product and allow to dry without wiping for children under 6, use only under adult supervision not recommended for infants

Inactive ingredients

Inactive Ingredient Water(Aqua), Acrylates/C10 30 alkyl arylate crosspolymer, Glycerin, Triethanolamine, Fragrance (Parfum), Tocopheryl Acetate, Aloe barbadensis-

leaf extract, Denatonium Benzoate, Phenoxyethanol, Ethylhexylglycerin.

Package Label - Principal Display Panel



HAND SANITIZER

alcohol gel

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51706-902 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | |
|--|-------------------|-----------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII: 3K9958V90M) | ALCOHOL | 62 mL in 100 mL | |

| Inactive Ingredients | | |
|---|----------|--|
| Ingredient Name | Strength | |
| CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) | | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | |
| WATER (UNII: 059QF0KO0R) | | |
| TROLAMINE (UNII: 903K93S3TK) | | |
| .ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | | |

| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | | |
|---------------------------------------|--------------------|--|
| DENATONIUM BENZOATE | (UNII: 4YK5Z54AT2) | |

| F | Packaging | | | | |
|---|----------------------|---|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:51706-902- 01 | 975 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/27/2020 | | |
| 2 | NDC:51706-902- 02 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/27/2020 | | |
| 3 | NDC:51706-902- 03 | 89 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/27/2020 | | |
| 4 | NDC:51706-902- 04 | 236 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/27/2020 | | |

| Marketing Information | | | | |
|-----------------------|-----------------|-------------------------|---|-------------------------|
| | Marketir Dat | Marketing Start Date | Application Number or Monograph Citation | Marketing Category |
| | | 05/27/2020 | part333A | OTC monograph not final |
| | | 05/27/2020 | | OTC monograph not |

Labeler - Landy International (545291775)

| Establishment | | | | |
|---------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Landy International | | 545291775 | manufacture(51706-902) | |

Revised: 3/2022 Landy International