PURMIST- benzalkonium cl liquid MKR International 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.

Hand Sanitizer

Active Ingredient

Benzalkonium Cl 0.13%

Purpose

Antiseptic

Uses

Leave on hand sanitizer to decrease harmful bacteria on the skin.

Warnings

For external use only.

DO NOT USE

in or near eyes.

Stop use and ask a doctor if

redness or irritation develop or persist for more than 72 hours.

Keep out of reach of children

unless under adult supervision. If swallowed get medical help or contact a Poison Control Center right away.

Directions

- Spray as needed
- Rub hands together covering all areas, including fingernail areas thoroughly

Other Information

store at 2° C to 40° C (35.6°F to 104° F)

Inactive Ingredients

polysorbate 80, proprietary blend of natural botanical oils, water

Dosage & Administration

300+ Sprays

Principal Display Panel



PURMIST

benzalkonium cl liquid

| Product Information | | | | |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50353-105 | |
| Route of Administration | TOPICAL | | | |

Active Ingredient/Active Moiety Ingredient Name BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y) BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)

| Inactive Ingredients | | |
|-----------------------------------|----------|--|
| Ingredient Name | Strength | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | | |
| WATER (UNII: 059QF0KO0R) | | |

| Packaging | | | |
|-------------------------------|---|-------------------------|-----------------------|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:50353- 105-50 | 60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 04/26/2021 | |

| Marketing Information | | | | |
|-------------------------|---|-------------------------|-----------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part333E | 04/26/2021 | | |
| | | | | |

Labeler - MKR International Inc (243605685)

| Establishment | | | | |
|------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| McKenna Labs Inc | | 090631412 | manufacture(50353-105) | |

Revised: 4/2022 MKR International Inc