

AVENGERS MARVEL HAND SANITIZER- benzalkonium chloride gel Shenzhen Lantern Science 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.

☐Active Ingredient

Benzalkonium Chloride 0.1%

☐Purpose:☐ Antibacterial

☐Use

To decrease bacteria on the skin that could cause disease.

Keep out of reach of children.

☐Warnings

- for external use only-hands.
- keep out of eyes. avoid contact with broken skin.
- stop use and ask a Doctor if irritation or redness develops.
- do not inhale or ingest. if swallowed, get medical help or contact a poison control center right away.

☐Directions

- Rub a dime sized drop into hands.
- For children under 6 use under adult supervision.

☐Inactive Ingredients

water (aqua/eau), glycerin, coceth-7, PPG-1-PEG-9 lauryl glycol ether, carbomer, hydrogenated castor oil, fragrance (parfum).

☐May Contain

Red 40 (CI 16035), Red 33 (CI 17200), Blue 1 (CI 42090), Yellow 5 (CI 19140).

Avengers Marvel Hand Sanitizer



AVENGERS MARVEL HAND SANITIZER

benzalkonium chloride gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:54860-039 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------|-------------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 1 g in 59 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| COCETH-7 CARBOXYLIC ACID (UNII: 35KO064932) | |
| CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E) | |
| PEG-40 CASTOR OIL (UNII: 4ERD2076EF) | |
| PPG-1-PEG-9 LAURYL GLYCOL ETHER (UNII: 5R8J43K25L) | |

Product Characteristics

| | | | |
|-----------------|---|---------------------|--|
| Color | red (red 40) , red (Red 33) , blue (Blue 1) , yellow (Yellow 5) | Score | |
| Shape | | Size | |
| Flavor | BLUEBERRY, CHERRY, LEMON, BERRY, GRAPE | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:54860-039-01 | 59 g in 1 BOTTLE; Type 0: Not a Combination Product | 08/10/2016 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E | 08/10/2016 | |

Labeler - Shenzhen Lantern Science Co., Ltd. (421222423)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------------|---------|-----------|------------------------|
| Shenzhen Lantern Science Co., Ltd. | | 421222423 | manufacture(54860-039) |

Revised: 8/2016

Shenzhen Lantern Science Co., Ltd.