

**SANITELLE MOISTURIZING HAND SANITIZER WITH MACADAMIA OIL-  
alcohol gel  
BENTUS LABORATORII, OOO**

*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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**Active Ingredient(s)**

Alcohol 80% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

**Warnings**

For external use only. Flammable. Keep away from heat or flame

**Do not use**

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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**Directions**

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

## Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

## Inactive ingredients

Water, Propylene Glycol, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Macadamia Ternifolia Nut Oil, Fragrance

## Package Label - Principal Display Panel



50 mL NDC: 80068-007-50

**Distributed by:** Flex Technologies, Inc, 10432 Balls Ford Rd. Suite 300, Manassas, VA 20109, USA

## SANITELLE MOISTURIZING HAND SANITIZER WITH MACADAMIA OIL alcohol gel

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:80068-007 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength | Strength          |
|--|-------------------|-------------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL           | 66.2 mL in 100 mL |

**Inactive Ingredients**

| Ingredient Name   | Strength          |
|---|-------------------|
| MACADAMIA OIL (UNII: 515610SU8C)                            |                   |
| GLYCERIN (UNII: PDC6A3C0OX)                                 | 1.45 mL in 100 mL |
| WATER (UNII: 059QF0KO0R)                                    |                   |
| CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO) |                   |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                         |                   |
| TROLAMINE (UNII: 9O3K93S3TK)                                |                   |

**Packaging**

| # | Item Code        | Package Description                                  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:80068-007-50 | 50 mL in 1 BOTTLE; Type 0: Not a Combination Product | 02/19/2021           |                    |

**Marketing Information**

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A                                 | 02/19/2021           |                    |

**Labeler** - BENTUS LABORATORII, OOO (354757383)**Establishment**

| Name                    | Address | ID/FEI    | Business Operations    |
|-------------------------|---------|-----------|------------------------|
| BENTUS LABORATORII, OOO |         | 354757383 | manufacture(80068-007) |

Revised: 2/2021

BENTUS LABORATORII, OOO