

## **SANITELLE HAND SANITIZER AROMA MANGO- alcohol spray 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

Aqua, Glycerin, Propylene Glycol, Tocopherol, Aloe Barbadensis Leaf Juice, Parfum, Limonene, CI 15985

## Package Label - Principal Display Panel



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

## SANITELLE HAND SANITIZER AROMA MANGO

alcohol spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80068-010
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80068-010-01	42 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/27/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/27/2021	

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

### Establishment

Name	Address	ID/FEI	Business Operations
BENTUS LABORATORII, OOO		354757383	manufacture(80068-010)

Revised: 4/2021

BENTUS LABORATORII, OOO