

SANITELLE HAND SANITIZER AROMA OF COFFEE- 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.

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.

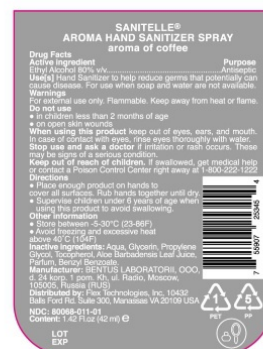
Other information

- 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, Benzyl Benzoate

Package Label - Principal Display Panel



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

SANITELLE HAND SANITIZER AROMA OF COFFEE

alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80068-011
Route of Administration	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		
GLYCERIN (UNII: PDC6A3C00X)		1.45 mL in 100 mL		
WATER (UNII: 059QF0KO0R)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
TOCOPHEROL (UNII: R0ZB2556P8)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
BENZYL BENZOATE (UNII: N863NB338G)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80068-011-01	42 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/27/2021	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/27/2021		

Labeler - BENTUS LABORATORII, OOO (354757383)

Establishment

Name	Address	ID/FEI	Business Operations
BENTUS LABORATORII, OOO		354757383	manufacture(80068-011)

Revised: 3/2021

BENTUS LABORATORII, OOO