SANITELLE ADVANCED HAND SANITIZER WITH ALOE- 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.

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.

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

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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.

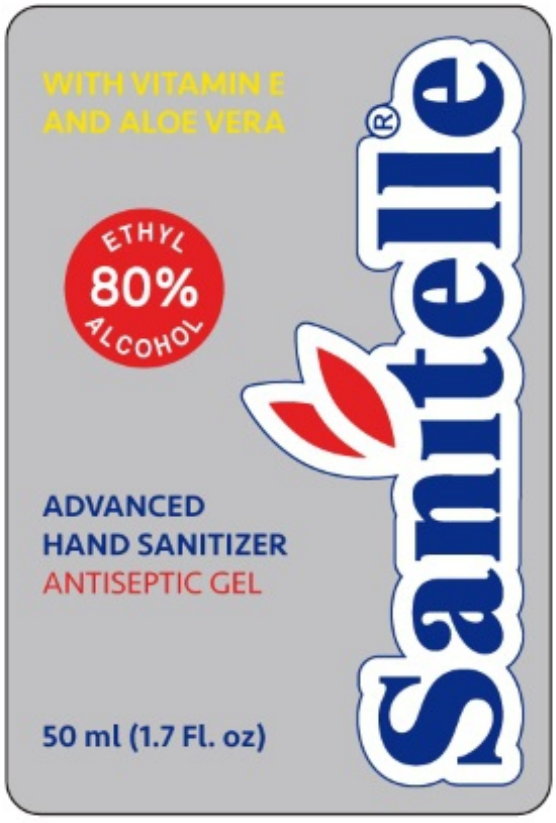
Other information

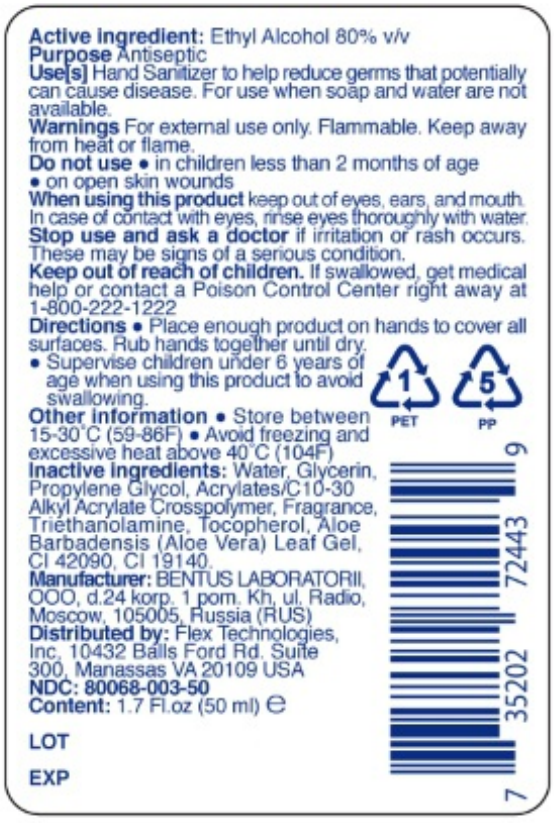
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

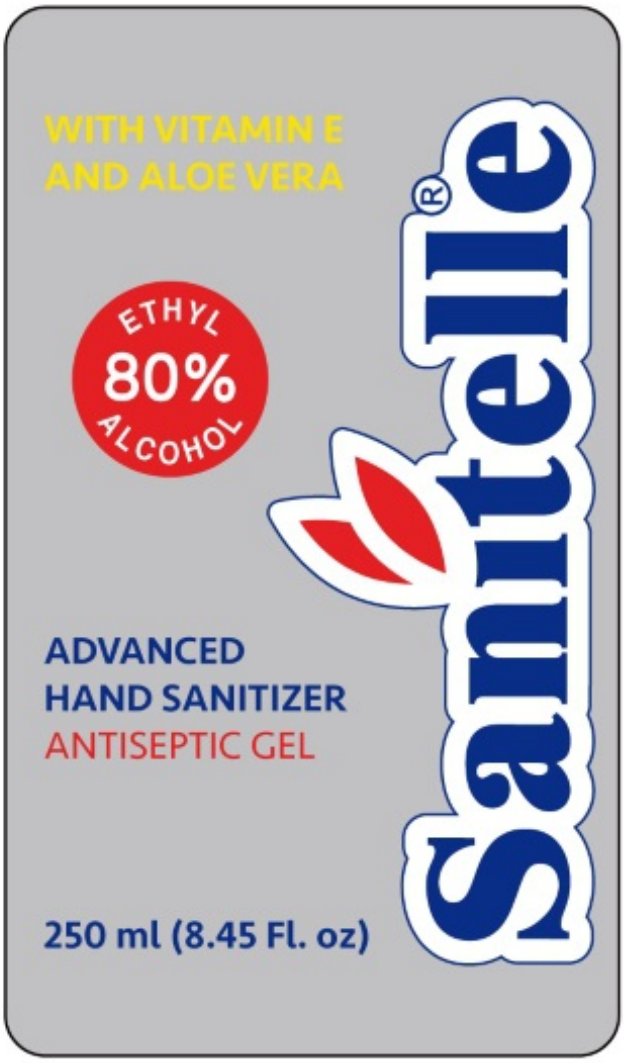
Water, Propylene Glycol, Glycerin, , Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Tocopherol, Aloe Barbadensis (Aloe Vera) Leaf Gel, CI 42090, CI 19140, Fragrance

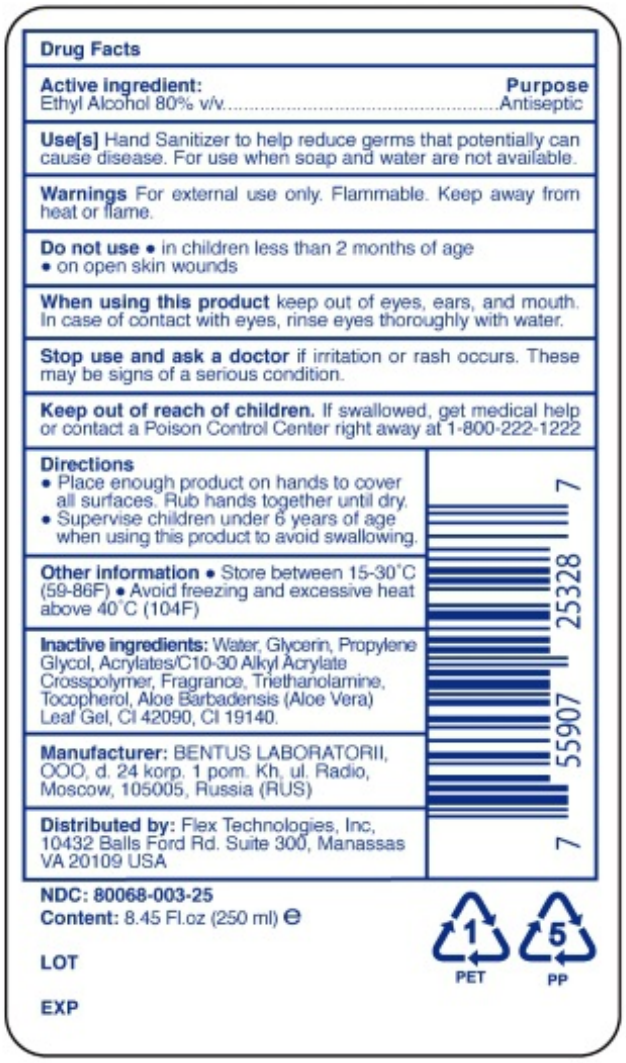
Package Label - Principal Display Panel





50 mL NDC: 80068-003-50





250 mL NDC: 80068-003-25

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

SANITELLE ADVANCED HAND SANITIZER WITH ALOE

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80068-003
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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
TOCOPHEROL (UNII: R0ZB2556P8)	
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)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80068-003-50	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/19/2021	
2	NDC:80068-003-25	250 mL in 1 BOTTLE, PUMP; 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(80068-003)

Revised: 2/2021 BENTUS LABORATORII, OOO