BACTIVE HAND SANITIZER- ethyl alcohol gel
Zuru LLC

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)

Ethyl Alcohol 70%.

Purpose

Antiseptic

Use

- For handwashing to decrease bacteria on the skin
- Recommended for repeat use

Warnings

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

When using this product

■ keep out of eyes. In case of contact with eyes, flush thoroughly with water.

■ avoid contact with broken skin.

■ do not inhale or ingest.

Stop use and ask a doctor

- If irritation and redness develop.
- If condition persists for more than 72 hours consult a doctor.

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

Directions

- wet hands thoroughly with product and allow to dry without wiping
- for children under 6, use only under adult supervision
- not recommended for infants

Other information

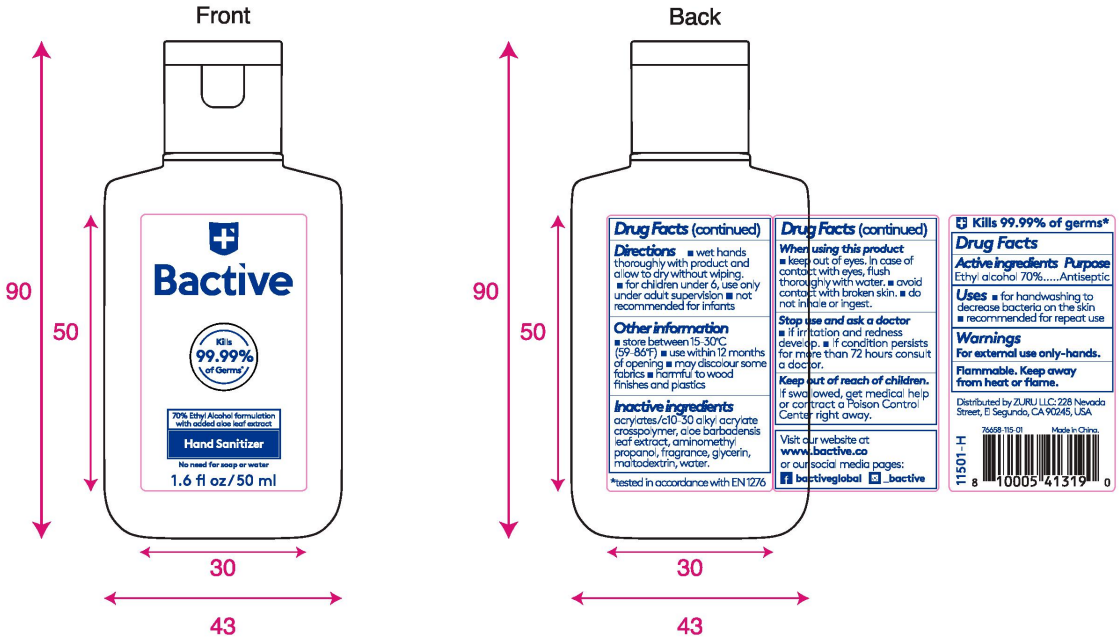
- Store between 15-30C (59-86F)
- use within 12 months of opening
- may discolour some fabrics
- harmful to wood finishes and plastics

Inactive ingredients

acrylates/c10-30 alkyl acrylate crosspolymer, aloe barbedensis leaf extract, aminomethyl propanol, fragrance, glycerin, maltodextrin, water

Package Label - Principal Display Panel

50 mL



500 mL

2L

USA version 16 April 2020

Pantone:
2146C diecut
白PE实色贴

BACTIVE HAND SANITIZER

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76658-115
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76658-115-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/17/2020	
2	NDC:76658-115-09	2000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/17/2020	
3	NDC:76658-115-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/17/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/17/2020	

Labeler - Zuru LLC (080435986)

Establishment

Name	Address	ID/FEI	Business Operations
Opal Cosmetics (Huizhou) Limited		528178475	manufacture(76658-115) , label(76658-115)

Revised: 6/2020 Zuru LLC