MI- benzalkonium chloride hs solution Infinity Manufacturing of America, 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.

SPL Unclassified Section

This is hand sanitizer manufactured according to OTC Monograph part 333a

Purpose

Antiseptic, Hand Sanitizer

- FOR EXTERNAL USE ONLY
- DO NOT USE ON CHILDREN UNDER 2 MONTHS OF AGE

WHEN USING THIS PRODUT

- KEEP OUT OF EYES, EARS AND MOUTH
- IN CASE OF CONTACT WITH EYES, RINSE EYES THPROUGHLY WITH WATER
- STOP USE AND CONTACT A PHYSICIAN IF IRRITATION OR

RASH OCCUR

KEEP OUT OF REACH OF CHILDREN

IF SWALLOWED, CALL POISON CONTROL IMMEDIATELY

Do Not Use-OTC

on children less than 2 mos in age on open skin wounds.

When Using Section

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 Section

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

Keep Out of Reach of Children

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

PLACE PRODUCT IN HANDS TO COVER ALL SURFACES, RUB

TOGETHER UNTIL DRY

CHILDREN UNDER 6 YEARS OF AGE SHOULD BE SUPERVISED

WHILE USING PRODUCT

INACTIVE INGREDIENTS IONIZED WATER, CARBAMIDE

Storage and Handling

Store between 15-30C (59-86F)

Avoid freezing and excessive heat above 40C(104F)

Inactive Ingredients

Ionized Water, Carbamide

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,

BENZALKONIUM CHLORIDE 0.13% v/v.....ANTIBACTERIAL

Active Ingredients

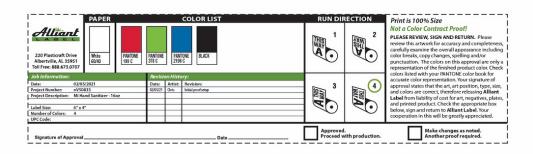
BENZALKONIUM CHLORIDE 0.13% v/v.....ANTIBACTERIAL

Uses

HAND SANITIZER TO DECREASE BACTERIA ON THE SKIN RECOMMENDED FOR REPEATED USE

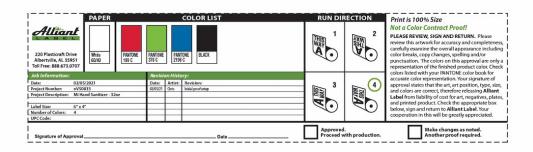
473ml NDC:81563-013-16





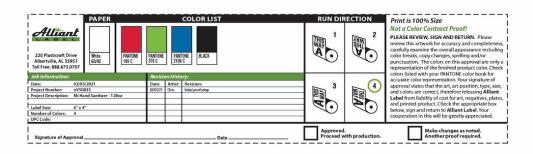
946ml NDC:81563-013-32





3785 ml NDC: 81563-013-00





236ml NDC: 81563-013-08



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benzalkonium chloride hs solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81563-013(NDC:78003-120)
Product Type	HOMAN OTC DIVOC	itelli code (Source)	NDC.01303-013(NDC.70003-120)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.0013 g in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
UREA (UNII: 8W8T17847W)			
WATER (UNII: 059QF0KO0R)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:81563- 013-08	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/23/2021		
2	NDC:81563- 013-16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/23/2021		
3	NDC:81563- 013-32	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/23/2021		
4	NDC:81563- 013-00	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/23/2021		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/23/2021	

Labeler - Infinity Manufacturing of America, LLC (117711498)

Registrant - Bama-Bio Tech Corporation (117525750)

Establishment				
Name	Address	ID/FEI	Business Operations	
Infinity Manufacturing of America		117711498	relabel(81563-013)	

Revised: 2/2021 Infinity Manufacturing of America, LLC